

1 FEDERAL TRADE COMMISSION

2 I N D E X (PUBLIC RECORD)

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4 WITNESS: DIRECT CROSS REDIRECT RECROSS

5 Levy 8256 8303 (SP) 8423

6 8380 (US)

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8 EXHIBITS FOR ID IN EVID

9 Commission

10 None

11 Schering

12 None

13 Upsher

14 None

15 OTHER EXHIBITS REFERENCED PAGE

16 Commission

17 CX 540 8307

18 CX 576 8266

19 CX 881 8280

20 CX 1775 8258

21 CX 1777 8292

22 Schering

23 SPX 613 8263

24 SPX 872 8351

25 SPX 1318 8339

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1	Schering	
2	SPX 1319	8349
3	SPX 1320	8354
4	SPX 1331	8356
5	SPX 1333	8360
6	SPX 1334	8370
7	SPX 1335	8362
8	SPX 1337	8372
9	Upsher	
10	USX 329	8399
11	USX 595	8279
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FEDERAL TRADE COMMISSION

In the Matter of:)
SCHERING-PLOUGH CORPORATION,)
a corporation,)
and)
UPSHER-SMITH LABORATORIES,) File No. D09297
a corporation,)
and)
AMERICAN HOME PRODUCTS,)
a corporation.)
-----)

Thursday, March 21, 2002

11:00 a.m.

TRIAL VOLUME 35

PART 1

PUBLIC RECORD

BEFORE THE HONORABLE D. MICHAEL CHAPPELL

Administrative Law Judge

Federal Trade Commission

600 Pennsylvania Avenue, N.W.

Washington, D.C.

Reported by: Susanne Bergling, RMR

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1 P R O C E E D I N G S

2 - - - - -

3 JUDGE CHAPPELL: Good morning, everyone.

4 ALL COUNSEL: Good morning, Your Honor.

5 JUDGE CHAPPELL: Let's reconvene docket 9297.

6 Who's up?

7 MR. SILBER: Complaint counsel, Your Honor,

8 call Dr. Nelson Levy in rebuttal.

9 JUDGE CHAPPELL: Okay, all right.

10 Raise your right hand, please, before you get

11 comfortable.

12 Whereupon--

13 NELSON L. LEVY

14 a witness, called for examination, having been first

15 duly sworn, was examined and testified as follows:

16 JUDGE CHAPPELL: Thank you, have a seat.

17 State your name for the record.

18 THE WITNESS: Nelson Louis Levy.

19 JUDGE CHAPPELL: Go ahead, Mr. Silber.

20 MR. SILBER: Your Honor, I have distributed to

21 Dr. Levy and respondents' counsel two binders we are

22 going to be using today. We are going to be pulling

23 them up electronically. I have a copy for you, if you

24 like, but I assure you we will pull each of these up

25 electronically.

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1 JUDGE CHAPPELL: Just so I can see them, that's
2 all I need.

3 DIRECT EXAMINATION

4 BY MR. SILBER:

5 Q. Dr. Levy, good morning.

6 A. Good morning.

7 Q. In direct, you testified that the \$60 million
8 payment from Schering to Upsher was not for Niacor-SR.

9 A. That's correct.

10 Q. Was one of the three points you made underlying
11 that opinion concerning due diligence for Niacor-SR?

12 A. Yes, it did.

13 Q. Did you reach that opinion because Schering's
14 due diligence was strikingly superficial?

15 A. Yes.

16 Q. Since you gave us your testimony during our
17 case in chief, have you had the opportunity to review
18 the trial testimony of Mr. Audibert and Mr. Lauda
19 concerning whether Schering conducted due diligence on
20 Niacor-SR?

21 A. Yes.

22 Q. And what is your understanding from that
23 testimony as to whether Schering conducted due
24 diligence on Niacor-SR?

25 A. It didn't change my opinion.

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1 Q. What is your understanding of their testimony
2 as to whether they conducted due diligence?

3 A. Oh, I'm sorry.

4 As I understand it, I think that they
5 maintained that Niacor-SR was a straightforward drug
6 and hence required no significant due diligence.

7 Q. Let me take you to a portion of Mr. Lauda's
8 testimony on this point, and Paula, if you could pull
9 that up.

10 If we could focus in on Mr. Lauda's testimony
11 in respondents' case in defense, transcript at page
12 4347, and if we could just pull up that page, and Dr.
13 Levy, here there's a question posed at the top of line
14 one saying:

15 "QUESTION: Did you reach a conclusion as to
16 whether this Niacor licensing opportunity is worth \$60
17 million to Schering?"

18 And then there's an exchange of a couple
19 questions and answers, then at line 8:

20 "QUESTION: What was the basis for that
21 conclusion?"

22 Let me just read Mr. Lauda's answer:

23 "The basis for the conclusion was that this,
24 that the financials and analysis that Jim made, told us
25 that we had a product that, number one, was rather

1 straightforward in the marketplace, it -- it was well
2 known, it's been in the market for 20 years, efficacy
3 proven. We had a sustained release technology that we,
4 Schering-Plough, were familiar with and was kind of
5 standard in the industry, so we knew we had a product
6 that worked."

7 Is this part of the testimony that you were
8 talking about?

9 A. Yes, sir.

10 Q. In your opinion, was Niacor-SR a
11 straightforward licensing opportunity?

12 A. Anything but.

13 Q. And have you prepared a slide summarizing your
14 opinion regarding this issue?

15 A. Yes, I have.

16 Q. Okay. Paula, if you could pull up what has
17 been marked for identification as CX 1775, and at this
18 point, Dr. Levy, I would ask you just to briefly go
19 through these points, and we can go through them in
20 more detail afterwards.

21 A. Well, I listed the four points. I think that
22 first of all, simply stated, as the slide says, niacin
23 is not Niacor-SR, and so one really shouldn't confuse
24 the two.

25 Secondly, there were myriad known problems with

1 all sustained release forms of niacin, and that would
2 make this anything but a straightforward evaluation.

3 Thirdly, Niacor-SR had been examined by 50-some
4 odd other companies in the European community, and they
5 certainly didn't find it straightforward. And then
6 there were --

7 MS. SHORES: Objection, Your Honor. I'm sorry,
8 objection as to how other companies viewed Niacor-SR as
9 to whether it was straightforward or not. I don't
10 think that this witness is in a position to tell us
11 about what they thought.

12 MR. SILBER: Your Honor, in the portion of the
13 transcript of Mr. Lauda we read through before, Mr.
14 Lauda stated that Niacor-SR was straightforward in the
15 marketplace. Now, in looking at that statement by Mr.
16 Lauda and generally Schering's position in the
17 litigation now that Niacor-SR was a straightforward
18 licensing opportunity and thus significant due
19 diligence wasn't necessary, Dr. Levy has looked at that
20 statement and examined evidence in the record to
21 establish his opinion that Niacor-SR, in fact, was not
22 straightforward.

23 One thing that he has looked at on this issue
24 as to whether it's straightforward in the marketplace
25 is what other companies reviewed and what they

1 determined when they looked at Niacor-SR.

2 JUDGE CHAPPELL: Okay, let me just save us some
3 time. I don't need you testifying.

4 MR. SILBER: Okay, Your Honor.

5 JUDGE CHAPPELL: If you are going to ask that
6 question, you need to lay a foundation. Sustained.

7 MR. SILBER: At this point, Your Honor, we are
8 going to -- I am going to go through these points in
9 some detail with Dr. Levy. When we come to that third
10 point, I will make sure to lay a foundation before we
11 go into it further.

12 JUDGE CHAPPELL: Okay, and regarding that
13 objection, when a witness said somebody thought
14 something was straightforward, I understand the source,
15 and if there is no foundation there for that kind of
16 statement, I'll disregard it.

17 MS. SHORES: Thank you, Your Honor.

18 JUDGE CHAPPELL: Not just for this witness but
19 for any witness who's testifying.

20 MR. SILBER: Thank you, Your Honor.

21 BY MR. SILBER:

22 Q. Dr. Levy, could you move on to your fourth
23 point?

24 A. The fourth point is there were myriad
25 unanswered questions that occurred to me and -- both

1 from the documents that were reviewed by Mr. Audibert
2 and the multitude of documents that had been available
3 to Schering at the time they made the decision that I
4 had the opportunity to examine.

5 Q. And for these reasons, you have concluded that
6 Niacor-SR was not straightforward?

7 A. Yes.

8 Q. Okay. Let's go to your first point in more
9 detail, and that first point is that -- is don't
10 confuse niacin with Niacor-SR. Can you elaborate on
11 that point?

12 A. Yes, certainly. I mean, niacin's a vitamin.
13 Niacin's been around -- Mr. Lauda said 20 years, it's
14 been around a lot longer than 20 years. It's been on
15 the market. It's sold in various forms. Quite --
16 almost diametrically opposed to that is the reality
17 that all the sustained release forms of niacin up to
18 that point in time had been quite significantly toxic
19 and had not been on the market, and so to say that --
20 to extrapolate from what immediate release niacin was
21 or wasn't to what Niacor was or wasn't was, you know,
22 comparing, you know, camels to elephants.

23 Q. Paula, if you could pull Mr. Lauda's testimony
24 up again, if we could pull up page 4347 again, I think
25 you are commenting on some of the language here at line

1 12 where Mr. Lauda says it was well known, it's been in
2 the market for 20 years, efficacy proven.

3 What was well known 20 years ago about niacin?

4 A. About niacin or Niacor?

5 Q. Niacor.

6 A. Nothing.

7 Q. Why is that?

8 A. Well, it hadn't been on the market at all. So,
9 I think that the statement that anything even remotely
10 like Niacor-SR had been on the market for 20 years is
11 patently spurious.

12 Q. Let's go to the next line of Mr. Lauda's
13 testimony, the next full sentence at line 14. It says:

14 "We had a sustained release technology that we,
15 Schering-Plough, were familiar with and was kind of a
16 standard in the industry."

17 Now, how would Schering's familiarity with its
18 own sustained release technology relate to Schering's
19 claim that Niacor-SR's sustained release mechanism is
20 straightforward?

21 A. A few years before Schering-Plough had
22 purchased a company called Key, Key Pharmaceuticals,
23 that had some sustained release technology. This
24 sustained release technology was Key's sustained
25 release technology. I'm sure Schering was familiar

1 with Key's sustained release technology. That has
2 nothing to do whatsoever with the -- having familiarity
3 with somebody else's sustained release technology.

4 In fact, each of these -- the sustained release
5 technologies involving the Kos product, involving the
6 Upsher product, involving the Key products, were all
7 different technologies. In fact, they're all patented
8 technologies. So, obviously the PTO has thought them
9 to be different.

10 So, for someone to maintain that it knew all
11 about Upsher-Smith's sustained release technology based
12 on their knowing something about their own technology
13 is, again, exceedingly misleading and totally spurious.

14 Q. If you could open your first binder and turn to
15 SPX 613, and Paula, if you could pull up that document.

16 A. This is the larger of the two binders?

17 Q. It's the other one.

18 A. The other one, okay.

19 Q. And it's SPX 613.

20 A. Okay.

21 Q. And have you reviewed this document?

22 A. Yes, I have.

23 Q. And what is this document?

24 A. This is a publication by a David Capuzzi and
25 several other authors entitled "Efficacy and Safety of

1 An Extended-Release Niacin (Niaspan): A Long-Term
2 Study."

3 Q. Was this an article relied upon by Dr. Horovitz
4 in his report for Schering?

5 A. I believe it was.

6 Q. Okay. And can you tell us more generally what
7 this article concerns?

8 A. Yes, it was a -- it -- as its name -- is its
9 title implies, it was a discussion of the efficacy and
10 safety of Niaspan, the Kos product, and what was -- and
11 this particular study emphasized the fact that Niaspan
12 had now been in patients -- in significant numbers of
13 patients for up to two years. They had 48-month and
14 96-month data -- I'm sorry, 48-week and 96-week data on
15 Niaspan.

16 Q. Okay. And when was this article published?

17 A. In 1998.

18 Q. So, this was after Niaspan -- Niaspan was
19 approved by the FDA?

20 A. Yes, sir.

21 Q. And in general, what does this article indicate
22 about the medical community's views on sustained
23 release niacin drugs in 1998?

24 A. I think one of the points that they make is
25 that prior to Niaspan, the medical community had been

1 quite negative on any of the sustained release forms of
2 niacin, and they make the point that Niaspan was the
3 exception to the rule, that Niaspan had -- did have
4 safety and efficacy and was approved as such by the
5 Food and Drug Administration, while all -- all the
6 previous sustained release forms of niacin had failed
7 in that regard.

8 Q. Let's look in the article to page 79.

9 A. Okay.

10 Q. Which is -- I think it's the sixth page of the
11 study.

12 A. Yes, I have it, sir.

13 Q. Okay. And if you could look at the first full
14 paragraph, and what does this discuss about the
15 author's views on Niaspan relative to other sustained
16 release niacin drugs?

17 A. I think it's more or less what I just said. It
18 says that Niaspan is the first extended release
19 preparation of niacin approved by the FDA as safe and
20 effective. In general, other sustained release
21 preparations of niacin have raised various safety
22 issues, especially with regard to a greater frequency
23 and severity of gastrointestinal effects, particularly
24 hepatotoxicity.

25 Q. Okay. And from your review of this article,

1 what does it indicate about whether the evaluation of a
2 sustained release niacin drug was straightforward?

3 A. As I said, I mean, this is one of the points
4 that I think it is anything but straightforward. The
5 rule, at the time that Schering acquired Niacor -- the
6 rule not the exception -- the rule was that sustained
7 release forms of niacin were hepatotoxic, and whether
8 or not Niaspan was or was not, it was if anything an
9 exception to a rule, and so I don't think one relies
10 upon the exception. One generally would rely upon the
11 rule.

12 Q. Okay. Paula, if we could have the slide
13 summarizing Dr. Levy's opinion on whether Niacor-SR was
14 straightforward.

15 Okay, we just finished talking about your first
16 point. The second point says, "Known problems with
17 sustained-release niacin."

18 Have you reviewed any documents that indicate
19 that Schering knew of any problems with sustained
20 release niacin drugs prior to licensing Niacor-SR?

21 A. Yes.

22 Q. And if we could pull up CX 576.

23 A. Okay.

24 Q. And Paula, if you could just focus in on the
25 title of this.

1 Dr. Levy, is this one of the documents you have
2 reviewed on this point?

3 A. Yes, sir.

4 Q. And the title is, "A Qualitative Evaluation of
5 the Opportunity for Niaspan in Multiple Lipid
6 Disorders, Telephone Interviews With Lipid
7 Specialists," and what's the date of this document?

8 A. April of 1997.

9 Q. And was that two months before Schering
10 committed to pay \$60 million for Niacor-SR?

11 A. Yes, it was.

12 Q. And tell us what this document is.

13 A. This was a summary of telephone interviews that
14 Schering carried out with its panel of ten major lipid
15 experts or experts on hyperlipidemic drugs and
16 summarizes the opinions of these -- of their own ten
17 experts on this matter.

18 Q. Okay. And just to be clear, so this is
19 research commissioned -- Schering had commissioned.

20 A. Yes, sir.

21 Q. Okay. Let's turn back in the document to the
22 page with Bates number SP 020711.

23 A. Okay.

24 Q. And let me read you the text of paragraph 9.

25 "Physicians also voiced numerous concerns and

1 questions. They need 'compelling evidence' to support
2 the safety and side effect claims which 'go against our
3 experience.' They want to see data on use with a
4 statin and on use above two grams. They want more
5 information on the frequency and severity of flushing
6 during titration. They still consider Niaspan
7 difficult to use in terms of titration requirements,
8 patient counseling and liver enzyme monitoring. They
9 caution that successful marketing will require a
10 significant commitment to physician and patient
11 education."

12 What are the key points raised in this
13 paragraph by Schering's own panel of ten lipidologists?
14 And if you could just identify those key issues at this
15 point.

16 A. Yeah, I think there were four. First, the
17 words "compelling evidence," these guys were saying
18 that the body of evidence is against a sustained
19 release niacin, and so in order to turn around that
20 evidence or that perception, one needed compelling
21 evidence on this matter, not just a smattering.

22 Second, they wanted to see data, not just
23 dialogue, they wanted to see data on two particular
24 points.

25 MS. SHORES: Pardon me, Your Honor, objection.

1 If Dr. Levy has some independent basis for testifying
2 about what these guys were saying, then I don't think a
3 proper foundation has been laid. If he doesn't, then I
4 think that all he's doing is characterizing the
5 document.

6 MR. SILBER: Your Honor, Dr. Levy's testifying
7 to this document to explain what was known -- in
8 particular, what was known to Schering at this time,
9 and he is offering merely his understanding of what was
10 stated here as an expert relying on this document to
11 offer an opinion that Niacor-SR was straightforward.
12 He's simply using this in order to express his opinion
13 that the -- that the product was not straightforward at
14 this time.

15 MS. SHORES: Well, I renew my objection then.
16 He's just simply standing upon what's stated in the
17 document.

18 JUDGE CHAPPELL: Right. We need the witness to
19 tell us that, not you, meaning you need to lay a better
20 foundation. Sustained.

21 BY MR. SILBER:

22 Q. Dr. Levy, what is your understanding of the
23 statements made here by these physicians concerning
24 their need to see data?

25 A. My understanding --

1 MS. SHORES: Your Honor, I -- again, I object.
2 I mean, we can all read the document. I don't think
3 that a foundation has been laid for Dr. Levy to expand
4 on it.

5 JUDGE CHAPPELL: That's sustained. I need to
6 know why he has some basis for giving us his
7 understanding rather than just reading a document
8 which -- is this document in evidence?

9 MR. SILBER: Yes, it is, Your Honor.

10 MS. SHORES: Yes, Your Honor.

11 JUDGE CHAPPELL: Okay, but rather than him just
12 reading from it, we need to know how he has some
13 independent reason to have an understanding of this,
14 because we all can read it for our own understanding.

15 MR. SILBER: Okay.

16 BY MR. SILBER:

17 Q. Dr. Levy, in your work in the pharmaceutical
18 industry, have you ever sought to have market research
19 conducted or been involved in those efforts?

20 A. Yes, sir.

21 Q. And why do companies seek to have market
22 research conducted when they're looking at a drug?

23 A. There are a variety of reasons. I think that
24 from a scientific point of view, one wants to get the
25 opinions of those thought leaders that ultimately would

1 drive the utilization of the drug in the clinical
2 marketplace, and that's where I think Schering was
3 focused here, and this is quite typical. They sought
4 out a sizeable panel, ten -- you know, ten worldwide
5 experts, and sought their opinions, and these guys,
6 so-called thought leaders, would be thought to drive
7 the opinions of prescribing physicians in the field.

8 Q. Okay. And does the information here about
9 their need to see data, does that confirm your own
10 opinions regarding whether there was a need to see
11 additional data on Niacor-SR to determine whether or
12 not it was straightforward?

13 A. Yes.

14 Q. And if you could elaborate here again, you were
15 going through why they needed to see the data on a
16 statin and above two grams.

17 MS. SHORES: Objection, Your Honor. I don't
18 think Dr. Levy can expand on why they needed to see the
19 data. He can expand on why he wanted to see the data
20 or why he felt it was appropriate for someone to want
21 to see data, but I don't believe he can tell us as to
22 why these particular physicians wanted to see any
23 particular data.

24 MR. SILBER: Your Honor, I'm happy to withdraw
25 the question and rephrase.

1 JUDGE CHAPPELL: Thank you.

2 BY MR. SILBER:

3 Q. Dr. Levy, why would you have wanted to see more
4 data on the issues identified here?

5 MR. CURRAN: Objection, Your Honor, on the same
6 grounds, and I'd like voir dire if this witness is
7 going to testify as though he's a lipidologist.

8 MR. SILBER: Your Honor, Dr. Levy, I mean, when
9 we went through his qualifications during our case in
10 chief had discussed extensively his experience in doing
11 research and his familiarity with studies, and I think
12 that qualifies him to have an opinion as to what type
13 of data is necessary. He does not need to be a
14 lipidologist to offer an opinion on this.

15 JUDGE CHAPPELL: Well, Mr. Curran, I'm going to
16 make a ruling that I used to hate when I was on your
17 side of the Bench, and now I know why I always hated
18 it. I'm going to allow it for the weight rather than
19 the admissibility, and you're welcome to test his
20 training and qualifications in this area on your cross
21 exam.

22 MR. CURRAN: Very good, Your Honor, I can live
23 with that. I don't hate the ruling.

24 JUDGE CHAPPELL: Thank you.

25 BY MR. SILBER:

1 Q. Dr. Levy, in your opinion, why would there be a
2 need to see additional data on use with a statin and
3 above two grams?

4 A. I think that without, you know, focusing on any
5 particular area of scientific expertise, the
6 pharmaceutical industry lives on data. As a person
7 evaluating an opportunity, one is not particularly
8 moved by dialogue as much as he is by data, and there
9 were two very, very significant elements that were
10 germane to the use of this drug.

11 The first one was well acknowledged by Mr.
12 Audibert himself in his development of the potential
13 use of this drug, and that is the use of Niacor with a
14 statin. That was one of the things that was projected.
15 And so one of the elements that I think these experts
16 are pointing out and that I certainly also looked for
17 was any semblance of data at all on the use of Niacor
18 with a statin, and there's a reason, you know, for
19 that.

20 You have a drug -- you have two drugs with
21 similar -- so-called similar efficacies, that is, they
22 both lower cholesterol and do good things for that.
23 They also both had, regardless of all the debate that's
24 gone on in this courtroom about how much hepatotoxicity
25 Niacor-SR had, it had some. I mean, I think more, they

1 may think less, but the fact is it had some. The
2 statins also had some degree of hepatotoxicity.

3 The big question is -- and this is a vital
4 question -- is would there be synergistic toxicity,
5 that is, we know that the statins have a little bit of
6 hepatotoxicity, we know that Niacor has a little bit of
7 hepatotoxicity -- and as I say, I think a lot of
8 hepatotoxicity, but regardless, nobody denies that it
9 had some. The question is does one plus one equal two
10 or does one plus one equal 14? Not in efficacy, but in
11 safety, that is, in toxicity, and one cannot know that
12 without having data on this matter, and it's a vital
13 point. It's not a minor point. It is an absolute
14 vital point.

15 Now, the second point that these fellows point
16 out is use of the drug above 2000 milligrams.
17 Schering's people have testified that they had planned
18 to develop this drug I believe at 1500 milligrams.
19 There's some question they might have wanted to develop
20 it at 2000 milligrams, but we all know, without being a
21 lipidologist or expert therein, anybody in the
22 pharmaceutical industry knows that physicians use drugs
23 off label. They use drugs at higher doses than are in
24 the PDR and are -- and are indicated.

25 Most of the time, this is not a problem,

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1 because most of the time, the efficacy goes up a little
2 bit when you push the dose and the safety goes down a
3 little bit when you push the dose, and you just -- you
4 just accept that risk, because they both go up in
5 parallel.

6 But what sometimes happens is you have what's
7 called a very narrow therapeutic window; that is, the
8 dose range in which you can use the drug is very
9 narrow. So, they may have tested it at 2000
10 milligrams, but if a physician were to use it at 2500
11 milligrams or 3000 milligrams, the question is, does
12 the safety go up -- go down a little bit or does it go
13 like this (indicating).

14 Now, this happens a lot with drugs, this sort
15 of thing (indicating), and you've got to know that.
16 So, these guys are saying that we must see data on the
17 use of this drug above the level at which it is going
18 to be registered and labeled, because they know that
19 physicians are going to want that. Any drug company is
20 worried about that, because that's how lawsuits are
21 born.

22 People abuse a drug, use the drug at doses
23 slightly above the level, and you get into problems,
24 and you kill people, and you've got to know that. You
25 absolutely have to know that.

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1 MS. SHORES: Objection, Your Honor, narrative
2 answer, and also I believe that he strayed quite
3 frequently in his long answer into what "these guys,"
4 i.e., these ten lipidologists, knew or wanted to know.

5 JUDGE CHAPPELL: Well, as for the narrative,
6 this answer is out already. I know you were standing
7 halfway through the answer, but we do need to narrow
8 the questions a little bit to give opposing counsel a
9 chance to object.

10 MR. SILBER: Yes, Your Honor.

11 JUDGE CHAPPELL: The question asked for a broad
12 answer. Why would you need to see additional data on
13 use with a statin and above two grams?

14 MS. SHORES: And again, it's one thing for Dr.
15 Levy to testify as to what he wanted to know, what he
16 wanted to see, but to frame his answer in terms of what
17 these lipidologists wanted to know I think is
18 objectionable.

19 MR. SILBER: Your Honor, I'm happy to re-ask
20 the question, narrowing it to Dr. Levy providing his
21 opinion as to whether he would want to see data above
22 two grams.

23 JUDGE CHAPPELL: Okay, Mr. Silber. As I
24 indicated earlier, I'm going to disregard responses
25 that refer to what someone else thought unless I have

1 more information or foundation to base that answer on.

2 MR. SILBER: Okay.

3 JUDGE CHAPPELL: Go ahead. So, in that
4 respect, the objection is sustained in part and
5 overruled.

6 MS. SHORES: Thank you, Your Honor.

7 BY MR. SILBER:

8 Q. And just to make clear, the narrow question
9 here is what is your opinion as to whether you would
10 want to see additional data on use of niacin drugs
11 above two grams.

12 A. I think I just stated it as thoroughly as I
13 can. It's -- in my opinion, no responsible company,
14 and I really perceive Schering as a highly responsible
15 company, ever would market a drug without data above
16 the levels at which they were going to claim labeling.

17 MS. SHORES: Objection, move to strike,
18 nonresponsive.

19 JUDGE CHAPPELL: I don't find it to be
20 completely nonresponsive. I'll overrule that
21 objection.

22 BY MR. SILBER:

23 Q. Dr. Levy -- Paula, if we could have the slide
24 summarizing Dr. Levy's opinion on whether Niacor-SR was
25 straightforward.

1 Okay, your third point is, "Niacor-SR was not
2 straightforward for other companies."

3 In reaching your opinion that Niacor was not
4 straightforward in response to statements by Mr. Lauda
5 and Audibert on this issue, did you consider other
6 companies' review of the Niacor-SR licensing
7 opportunity?

8 A. Yes, I did.

9 Q. And what documents did you look at?

10 A. There were summary documents produced by a man
11 I believe named Mr. Pettit who had been commissioned by
12 Upsher-Smith to try to find a licensee in Europe. Then
13 there were a number of mostly letters, correspondence,
14 between Upsher and various of these companies regarding
15 their opinions on the drug.

16 Q. And you reviewed those documents to
17 determine -- to -- relating to your opinion as to
18 whether Niacor-SR was straightforward?

19 A. Yes, sir.

20 Q. And what did that exercise indicate to you as
21 to whether Niacor-SR was straightforward?

22 MS. SHORES: Objection, overbroad. If he's
23 going to testify about documents that he reviewed from
24 these other companies indicating that Niacor-SR wasn't
25 straightforward, I'd like to have a reference to the

1 actual document.

2 MR. SILBER: I'm -- Your Honor, there's a
3 variety of documents. I'm happy to bring one of them
4 up right now to show that Dr. Levy reviewed it.
5 There's probably 20-30 documents in the record on this
6 that Dr. Levy has looked at. I'm happy to bring one of
7 them up to show that he has knowledge of this document
8 and that he used that document for this purpose.

9 JUDGE CHAPPELL: So, you are going to withdraw
10 the last question?

11 MR. SILBER: Sure.

12 JUDGE CHAPPELL: All right.

13 BY MR. SILBER:

14 Q. Okay, if we could have USX 595.

15 A. Okay.

16 Q. And Dr. Levy, what is this document?

17 A. I believe this was a summary document that was
18 prepared by Mr. Pettit for Upsher summarizing his
19 progress to date in trying to find a licensee for
20 Niacor-SR in Europe.

21 Q. Okay. And what was the response from the
22 companies listed here regarding the licensing
23 opportunity for Niacor-SR?

24 MS. SHORES: Objection, compound, overbroad.
25 There's a lot of companies. I don't want to have to

1 stand here all day going through each company one by
2 one, but I do object to a generalization about what
3 this document says or what the companies thought
4 vis-a-vis Niacor-SR.

5 MR. SILBER: Your Honor, I can withdraw the
6 question and go to one document on a specific company
7 to show how Dr. Levy looked at this document.

8 JUDGE CHAPPELL: Okay, thank you.

9 BY MR. SILBER:

10 Q. Okay, if we could pull up CX 881.

11 Dr. Levy, have you reviewed this document?

12 A. Yes.

13 Q. And did you review this document in connection
14 with reaching your conclusion that Niacor-SR was not
15 straightforward?

16 A. Yes.

17 Q. And first, just to establish what this document
18 is, can you tell us what it is?

19 A. Yes, of the 50-some odd companies that were on
20 that list, there was one left that had not yet rejected
21 Niacor, and this was a company called Pierre Fabre, and
22 this was a document of -- it looks like a memo from --
23 an internal memo at Upsher-Smith summarizing their
24 meeting with Pierre Fabre.

25 Q. Okay. And what in this memo indicated to you

1 that Niacor-SR was not a straightforward licensing
2 opportunity?

3 A. Well, remember, putting it in context, this was
4 a very -- Pierre Fabre was still at a very preliminary
5 stage of its evaluation, and they had this first
6 meeting, and Pierre Fabre raised two of the obvious
7 concerns and questions about this product that had
8 been -- that had come forth in my review and the myriad
9 other reviews that companies had done, and the two
10 major issues that were -- that seemed to have been
11 raised in this meeting --

12 MS. SHORES: Your Honor -- I apologize for
13 interrupting, Dr. Levy, but given this last ruling
14 about my standing up and not getting the objection out
15 before the answer was finished, I'm going to have to
16 interrupt you.

17 Your Honor, again, I just don't think that this
18 is proper expert testimony, for Dr. Levy to testify
19 about what people at Pierre Fabre thought based on a
20 memo that somebody at Upsher-Smith wrote about a
21 meeting. I don't think he's offering any expertise
22 that would be helpful to the Court on any of the
23 relevant issues in doing so.

24 MR. SILBER: Your Honor, Dr. Kerr, who
25 testified for Upsher, relied on these same types of

1 documents for the position that there was documented
2 interest by other companies in Upsher-Smith. All Dr.
3 Levy is doing here is saying that based upon this
4 document, based upon Upsher's own internal summary,
5 there was indications that there were issues regarding
6 Niacor-SR to this company, and he's saying that based
7 upon expression of those concerns, he doesn't think
8 that Niacor-SR was straightforward.

9 MR. CURRAN: Your Honor, if I could just point
10 out that this witness is not designated as a rebuttal
11 witness to Dr. Kerr, and Dr. Kerr was rebutting Dr.
12 Bresnahan and his market test. So, I don't think the
13 Bresnahan/Kerr issue has any relevance to this
14 particular witness.

15 MR. SILBER: Your Honor, if I may, I'm not
16 indicating Dr. Levy is testifying in rebuttal to Dr.
17 Kerr. I'm just stating an example where an expert has
18 relied on a document just like this to reach his own
19 conclusions.

20 JUDGE CHAPPELL: Well, I am going to partially
21 sustain the objection, and I believe you've addressed
22 Mr. Curran's objection if you're saying he's not
23 rebutting Dr. Kerr. I understand his opinion that -- I
24 think you worded it he doesn't think Niacor-SR was
25 straightforward. I understand that. I understand

1 that's his opinion for what that's worth, and you've
2 given us what you think are some reasons for his basis
3 for that opinion.

4 MR. SILBER: Yes, Your Honor.

5 JUDGE CHAPPELL: So, we don't need to dwell on
6 that, okay?

7 MR. SILBER: Okay.

8 BY MR. SILBER:

9 Q. Dr. Levy, based upon your review of this
10 document and other documents concerning concerns raised
11 by other companies relating to Niacor-SR, based upon
12 those documents, is it your view that Niacor-SR was
13 straightforward?

14 MS. SHORES: Your Honor, again, I apologize for
15 raising the same objection over and over again, but to
16 this question I object on the basis I did before, which
17 is that it's overbroad. I don't know what documents
18 that Mr. Silber's talking about that document all these
19 concerns of other companies, and so I object to a
20 question that goes beyond a particular company that we
21 can see the document about.

22 JUDGE CHAPPELL: Well, Mr. Curran -- I'm sorry,
23 Ms. Shores, I'm going to overrule that, because our
24 friends the Federal Rules allow an expert witness to
25 give us an opinion without giving us all the data and

1 underlying assumptions, but you're allowed to get into
2 that on cross. So, it would fall on you to do that.

3 Go ahead.

4 MR. SILBER: Thank you, Your Honor.

5 Susanne, if we could get the question read
6 back, please.

7 (The record was read as follows:)

8 "QUESTION: Dr. Levy, based upon your review of
9 this document and other documents concerning concerns
10 raised by other companies relating to Niacor-SR, based
11 upon those documents, is it your view that Niacor-SR
12 was straightforward?"

13 THE WITNESS: Again, I think this document is
14 another example of how it was not straightforward in my
15 opinion. They raise -- there were a multitude of
16 reasons why it wasn't straightforward, and this
17 document just points out that they saw two of the more
18 prominent ones, and the question of the patent, whether
19 there was a patent, whether there wasn't a patent in
20 Europe, was a question that they raised and certainly
21 one that I've seen and others have seen, and then this
22 whole question of the elevated liver function studies,
23 which is something that's been discussed, you know, a
24 multitude of times here, and it was just obvious
25 that -- from this document that Pierre Fabre saw the

1 two most glaring concerns and would suggest that it was
2 not straightforward to them.

3 BY MR. SILBER:

4 Q. Okay. Paula, could we pull up the summary
5 slide again?

6 Dr. Levy, your last point here is that there
7 are many unanswered questions. When you say there are
8 unanswered questions, what time period are you
9 referring to?

10 A. I'm talking about at the time they made the
11 deal, at the time -- you know, June 17th or whatever it
12 was when they executed the deal, as far as I could see,
13 there were a multitude of unanswered questions that I
14 saw, both from the documents that Mr. Audibert reviewed
15 and a host of documents that I was able to review that
16 would have been available to Schering at the time and
17 that I did have the opportunity to examine.

18 Q. Okay. So, you have looked at documents that
19 existed prior to June 1997?

20 A. Yes, sir.

21 Q. Okay. And if you could look at the other
22 binder of documents you have up there, and if you could
23 just tell us generally what types of documents are in
24 here.

25 A. Yes, this is a binder full of correspondence

1 between Upsher-Smith and the FDA. When I started
2 looking into this question, I realized that the -- at
3 least to me and I think to most people, but I'll speak
4 for myself, in my instance, after looking at the
5 preliminary data that a company presents, really the
6 first thing that I want to see is what has gone on with
7 the FDA.

8 The Food and Drug Administration, you know,
9 carries out a -- you know, an examination, and it would
10 help guide my own questions in terms of looking at this
11 potential product to see what the FDA has said in the
12 course of its interaction with the -- you know, with
13 the potential licensor.

14 MS. SHORES: Your Honor, I object to this line
15 of questioning on two grounds. First of all, we were
16 just recently put on notice, within the past few days,
17 that Dr. Levy had reviewed the Upsher-Smith/FDA
18 correspondence file. I don't believe he offered an
19 opinion about documents from this file in his expert
20 report. In his deposition, he stated that he tried to
21 confine himself to the information that Schering did
22 review when it was looking at Niacor-SR. So, that's
23 one basis for my objection.

24 The other basis is that this is not among the
25 three topics that complaint counsel identified in their

1 brief that this witness was being brought back to
2 testify about. Those were, again, the state of the
3 knowledge in the industry about sustained release
4 niacins generally, Schering's knowledge on that topic,
5 and why a company's commitment to make an up-front
6 payment is different from their commitment to make
7 other kinds of payments.

8 MR. CURRAN: Your Honor, I join expressly in
9 those objections.

10 MR. SILBER: First, as to providing the notice
11 of these documents, as Ms. Shores stated, we did
12 provide the notice that Dr. Levy would rely upon them.
13 The reason Dr. Levy didn't rely upon these in his
14 initial report was because we didn't anticipate that
15 the other side was going to argue that the drug was not
16 straightforward.

17 In rebutting that point, Dr. Levy is going to
18 testify that there were documents existing that
19 Schering could have looked at that indicate from a
20 regulatory perspective that this was not
21 straightforward.

22 JUDGE CHAPPELL: Didn't you know that -- didn't
23 you know that when you filed your brief indicating the
24 reasons you were going to bring this witness back for
25 rebuttal?

1 MR. SILBER: Yes, Your Honor, and I do believe
2 that they are on notice. I mean, generally we said
3 that according to Schering's Mr. Lauda, niacin was
4 rather straightforward in the marketplace, and there
5 was very little risk of the drug not being approved.
6 We gave them that statement in this brief and cited to
7 where it was in the transcript, and Dr. Levy is
8 rebutting that point expressly.

9 MS. SHORES: May I approach the ELMO, Your
10 Honor?

11 JUDGE CHAPPELL: Yes.

12 MS. SHORES: Whoops -- can you? Thanks.

13 MR. SILBER: Oh, sorry.

14 MS. SHORES: Your Honor, referring to page 8 of
15 complaint counsel's brief, and what it says is -- they
16 do -- you know, they say that Lauda testified there was
17 little risk of it not being approved and that it was
18 straightforward. Then it says, "Dr. Levy will rebut
19 this new theory by providing his opinions regarding the
20 state of knowledge in the pharmaceutical industry
21 concerning sustained release niacin drugs and
22 Schering's knowledge of such information at the time of
23 its evaluation of Niacor-SR."

24 That's what it says in the brief, and that was
25 the purpose for which I raised this topic with Your

1 Honor, as you'll recall, the day after we heard
2 argument on this issue.

3 JUDGE CHAPPELL: Objection sustained.

4 MR. SILBER: May I have a moment, Your Honor?

5 JUDGE CHAPPELL: Yes.

6 (Counsel conferring.)

7 MR. SILBER: Your Honor, we would like to offer
8 a proffer on this subject and would request that we do
9 it by question and answer.

10 JUDGE CHAPPELL: Do you want to do it now or at
11 the end of your direct?

12 MR. SILBER: Whatever is your preference, Your
13 Honor.

14 JUDGE CHAPPELL: Why don't you wait and do it
15 at the conclusion of the direct exam.

16 MR. SILBER: Okay, thank you, Your Honor.

17 JUDGE CHAPPELL: You understand the rule allows
18 you to offer the answer to the question that I just
19 struck, that I'm disregarding, that I -- you know, the
20 objection I've sustained. That's what the rule says.

21 MR. SILBER: Okay.

22 JUDGE CHAPPELL: So, at this point all you
23 could do is let him answer the question based on the
24 objection I sustained, just so you understand what the
25 rule says.

1 MR. SILBER: Are you indicating that it is
2 solely that individual question?

3 JUDGE CHAPPELL: That's what the rule says in
4 our book, yes.

5 MR. SILBER: Okay, if I could have a moment
6 again, Your Honor, please?

7 JUDGE CHAPPELL: All right.

8 (Counsel conferring.)

9 MR. SILBER: Your Honor, there were subsequent
10 questions regarding this topic that I intended to go
11 into with Dr. Levy, and I wish to offer a proffer
12 regarding those questions also.

13 JUDGE CHAPPELL: Okay, just so we're clear,
14 Rule 3.43(g) states, in part, under Excluded Evidence,
15 "When an objection to a question propounded to a
16 witness is sustained, the questioner may offer a
17 specific offer of proof of what he expects to prove by
18 the answer of the witness, or the administrative law
19 judge may, in his discretion, receive and report the
20 evidence in full."

21 MR. SILBER: Okay.

22 JUDGE CHAPPELL: That's the rule. Now, I don't
23 construe it that narrowly, because I don't want to
24 stand here and listen to an objection on every question
25 in this line where you're going here. So, I will allow

1 you to do this at the end by question and answer within
2 this -- on this issue, on this topic, just for
3 expediency, but I just wanted to point out, we're
4 talking about this topic only, what you were going into
5 here.

6 MR. SILBER: Okay, certainly, Your Honor.

7 JUDGE CHAPPELL: All right, you may proceed.

8 MR. CURRAN: Your Honor, could I address that
9 point very briefly?

10 JUDGE CHAPPELL: Yes.

11 MR. CURRAN: Your Honor has been helpful in
12 pointing out the specific rule that governs this in the
13 rules of this proceeding. I'd just like to point out
14 that that rule says that the questioner may make a
15 specific offer of proof. It doesn't say anything about
16 the witness. So, I would submit an application of this
17 rule would require complaint counsel themselves to make
18 the offer and not in a specific Q&A format.

19 JUDGE CHAPPELL: Well, my theory on that is
20 this is for the purposes of appellate authorities, and
21 whether it's stated generally by the counsel offering
22 it or by the witness or by written declaration, it's
23 all the same to me. So, I'm not going to construe it
24 that narrowly. Thank you.

25 MR. CURRAN: Thank you, Your Honor.

1 BY MR. SILBER:

2 Q. Paula, if we could have the other summary
3 slide -- actually, I'm sorry.

4 Dr. Levy, have you reviewed the testimony of
5 Thomas Lauda regarding the payment structure of various
6 Schering licensing deals?

7 A. Yes. Yes, I have.

8 Q. And have you prepared -- have you reviewed a
9 slide prepared by Mr. Lauda regarding the total
10 investment in licensing deals?

11 A. Yes, I have.

12 Q. And have you prepared your own slide
13 summarizing your opinions in response to Mr. Lauda's
14 analysis?

15 A. Yes, I have.

16 Q. And Paula, if we could have that slide, please.
17 And for identification, this is marked as CX 1777.

18 Dr. Levy, if you could just briefly talk
19 through the points you make on this slide.

20 A. Well, I think the -- you know, the first point
21 is simply that regardless of what Mr. Lauda added or
22 didn't add to various and sundry bars, the \$60 million
23 was still the largest noncontingent licensing fee any
24 company in the entire industry had ever paid for any
25 drug at any time up to that time, and that point was

1 not at all negated by Mr. Lauda's slide.

2 The second point was one that -- it's a general
3 comment that Mr. Lauda added what we've referred to as
4 milestone payments and then R&D expenses to the -- you
5 know, to the bars above the line, and those are
6 different kinds of expenses, because a pharmaceutical
7 company, as would any company, needs and wants control
8 of its expenses, of its finances and of the data
9 generated in the course of carrying out development of
10 a drug, and so all of that -- all of those bars, if you
11 will, that Mr. Lauda added were all under the control
12 of the company, and ironically, in contrast, this
13 particular case that we've been discussing here, the
14 Niacor-SR license, is the absolute, unadulterated
15 epitome of the lack of control, the very thing that
16 companies don't want.

17 In fact, it's -- it couldn't be clearer that
18 the company made payments of I guess \$32 million long
19 after they knew the drug was dead, dead as a doornail.
20 This is why companies want control over these kinds of
21 payments. They're able to control their own destiny
22 and control the generation of data.

23 Q. If we can go to your third point, Dr. Levy.

24 A. I'm sorry.

25 The third point was that it makes the very

1 erroneous assumption that there would be no further
2 expenses on Niacor-SR. They added the anticipated, not
3 the real, the anticipated expenses for all the other
4 products, but they added nothing for Niacor, which I
5 think is very misleading and spurious.

6 MR. SILBER: Your Honor, at this time we are
7 going to need to go in camera. I am going to be using
8 some slides and documents that contain in camera
9 materials.

10 JUDGE CHAPPELL: All right, I'll need to ask
11 the public to leave the courtroom. We're going to go
12 into in camera session.

13 (The in camera testimony continued in Volume
14 35, Part 2, Pages 8446 through 8463, then resumed as
15 follows.)

16 JUDGE CHAPPELL: Our public has returned. You
17 may continue, Mr. Silber.

18 MR. SILBER: Thank you, Your Honor.

19 BY MR. SILBER:

20 Q. Now, Dr. Levy, in discussing in your view what
21 additional R&D expenses there may be, you had indicated
22 there may be other additional studies that Schering
23 might need to conduct. Is that right?

24 A. Yes.

25 Q. Okay. And what types of studies were you

1 referring to?

2 A. I think there were a number of things that I
3 looked for when I -- when I looked through the dossier
4 that Mr. Audibert had, and these questions were many,
5 and they're the sort of questions that I'm referring
6 to.

7 MS. SHORES: Objection, move to strike, Your
8 Honor, on the ground that, again, this is not within
9 the three topics that complaint counsel identified that
10 Dr. Levy was coming back to testify about. Nowhere in
11 their brief was identified the need for Dr. Levy to
12 come back and testify about the types of studies that
13 were required.

14 MR. SILBER: Your Honor, we are -- Paula, if
15 you could pull up the slide summarizing Dr. Levy's
16 opinion on this point. We are still discussing -- I'm
17 sorry, the next slide -- Dr. Levy's opinion that
18 this -- we are discussing Dr. Levy's opinion that the
19 \$60 million payment is still grossly excessive. That
20 is something that they have notice of. This is in
21 rebuttal to Mr. Lauda's analysis, including for other
22 deals contingent fees and anticipated R&D.

23 Dr. Levy is still discussing in his view what
24 additional anticipated R&D there would have been
25 required for Niacor, and he, if allowed, is going to

1 testify about additional studies just like the European
2 studies he just discussed that would be required for
3 this drug in his view.

4 MS. SHORES: Your Honor, that's simply not in
5 their brief. Again, what the brief identifies as the
6 topics that Dr. Levy was coming to testify about
7 were -- was the knowledge of sustained release niacins
8 in the industry, what Schering knew on that topic, and
9 the difference between various sorts of licensing
10 payments as between up-front versus milestones, et
11 cetera.

12 MR. SILBER: And he's explaining about these
13 other types of payments.

14 MS. SHORES: This is a different topic.

15 MR. SILBER: Mr. -- and it's also directly in
16 rebuttal to Mr. Lauda's testimony when we asked him
17 about these additional expenses and he said there were
18 minimal, minimal additional costs, and he said it would
19 be an insignificant amount. Dr. Levy is responding to
20 that testimony, saying it's not minimal, minimal and
21 that it's not insignificant.

22 MS. SHORES: Again, I don't have any problem
23 with him talking about how various payments differ as
24 between noncontingent, contingent, et cetera. I think
25 we're getting into a different area when he starts

1 talking about the R&D that needed to be done with
2 Niacor. That's not in their brief. I'm happy to put
3 it back up for Your Honor.

4 JUDGE CHAPPELL: Well, I think we've heard a
5 lot of testimony from your side, Mr. Silber, that it
6 wasn't minimal and from the other side that it was
7 minimal or justified or contingent. Do you really need
8 to rebut that?

9 MR. SILBER: Your Honor, we would like to offer
10 this --

11 JUDGE CHAPPELL: I'm not sure we need to beat
12 the proverbial dead horse anymore.

13 MR. SILBER: Okay, Your Honor --

14 JUDGE CHAPPELL: For what it's worth, I will
15 allow it. I'll overrule the objection and allow him to
16 answer that, but let's move on.

17 MR. SILBER: Okay, I will keep this brief, Your
18 Honor.

19 BY MR. SILBER:

20 Q. Dr. Levy, can you just briefly describe what
21 types of additional studies might have been required?

22 A. Yes, I'll try -- I'll try to be brief. The --
23 I'm trying to organize my thoughts so I don't get as
24 long-winded as I usually am, Your Honor. I'm sorry.

25 JUDGE CHAPPELL: We don't want you to continue

1 to be the rambling man.

2 THE WITNESS: I follow you.

3 The key point here that to me or among the key
4 points that remain unanswered really are two. First,
5 looking at the data that they -- that they have
6 presented, all of the data that they've shown are
7 average data, you know, the LDL went down an average
8 amount, the HDL went up an average amount, there was X
9 incidence of elevated liver toxicity or elevated liver
10 enzymes, et cetera.

11 Now, the problem with that and the thing that
12 needs to be looked at is, for instance, let's take the
13 toxicity issue. Let's say -- whatever number it is,
14 let's say it's 5 percent of the patients had an
15 elevated liver enzyme elevation. Were all of those
16 five patients the patients that also got the good
17 effect on LDL? So that essentially do you have to have
18 a toxic effect to have a therapeutic effect or were
19 they random?

20 A clearer one would be, say, with the HDL and
21 the LDL. You know, the good thing is to have the HDL
22 go up and the LDL go down, and indeed, their average
23 data showed that they had that, the LDL went down and
24 the HDL went up, but what --

25 MS. SHORES: Your Honor, I have to object to

1 this as nonresponsive. I'm sorry, maybe he is getting
2 to the answer, but this is just extraordinary.

3 JUDGE CHAPPELL: He does continue to ramble,
4 doesn't he, Mr. Silber?

5 MR. SILBER: I can re-ask the question, and I
6 would --

7 JUDGE CHAPPELL: We need to give the other side
8 the opportunity to object when they feel it's
9 necessary. So, maybe he is answering the question, but
10 he seems to be going further than the scope of your
11 question.

12 MR. SILBER: Okay.

13 BY MR. SILBER:

14 Q. Dr. Levy, can you just specifically tell us
15 just briefly what types of studies, just the type of
16 study?

17 A. Okay, they have to correlate their good effects
18 and their bad effects. You know, there are bad effects
19 and there are good effects. If all the bad effects
20 occurred in the same patients that they're getting
21 their putative good effects, they don't have a drug. I
22 mean, I don't know how much more succinct I can be.
23 I'm trying to elaborate on that, and I think Ms. Shores
24 doesn't want truth, she wants rapidity, so --

25 MS. SHORES: I'll move to strike that, Your

1 Honor.

2 MR. CURRAN: I'll bear the burden of this
3 objection for rambling, Your Honor. The question was
4 what types of studies.

5 THE WITNESS: I'm trying to tell what types of
6 studies, but they need to have correlation between --

7 JUDGE CHAPPELL: Hang on, I have two objections
8 pending, Dr. Levy, not just one.

9 I am going to disregard the reference to Ms.
10 Shores and instruct you to keep that to yourself, Dr.
11 Levy, okay? And he is still going beyond the scope.
12 We don't need him to expound -- I think you were asked
13 a more direct question, okay, Doctor?

14 THE WITNESS: I don't know how to answer the
15 question succinctly --

16 BY MR. SILBER:

17 Q. Let me just ask one final wrap-up question
18 here.

19 Dr. Levy, the fact that Schering -- well, I'll
20 ask you two questions.

21 Did Schering evaluate whether there were
22 additional anticipated R&D expenses for Niacor-SR?

23 A. No.

24 Q. The fact that they didn't look to see whether
25 there were additional R&D expenses, what does that tell

1 you about the payment, the \$60 million payment, for
2 Niacor-SR?

3 A. I don't think it says anything about that. I
4 mean, the \$60 million payment speaks for itself, and
5 what additional payments they -- we're talking about
6 now what additional payments they might or might not
7 have had to make.

8 MR. SILBER: That's all I have, Your Honor.

9 If I could take a moment to review what I would
10 like to do on the proffer to try to keep it short?

11 JUDGE CHAPPELL: Go ahead.

12 (Counsel conferring.)

13 MR. SILBER: Your Honor, at this time, in order
14 to save time, we would offer the statement in writing,
15 and we will submit it with the other proffers that we
16 have offered previously.

17 JUDGE CHAPPELL: Okay, thank you.

18 How much anticipated cross do you have, Ms.
19 Shores?

20 MS. SHORES: Your Honor, it's hard to tell. I
21 might be able to narrow it substantially if I had time
22 to do that.

23 JUDGE CHAPPELL: So, would an hour give you
24 time to do that?

25 MS. SHORES: That certainly would, Your Honor.

1 JUDGE CHAPPELL: What about you, Mr. Curran?
2 Are you going to handle this?

3 MR. CURRAN: I am going to handle this, Your
4 Honor, after Ms. Shores, and I would anticipate about
5 half an hour, 45 minutes.

6 JUDGE CHAPPELL: Why don't we just go ahead and
7 take our lunch break now. We will reconvene at 1:30.

8 (Whereupon, at 12:30 p.m., a lunch recess was
9 taken.)

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1 AFTERNOON SESSION

2 (1:30 p.m.)

3 JUDGE CHAPPELL: Ms. Shores, you may proceed.

4 MS. SHORES: Thank you, Your Honor.

5 CROSS EXAMINATION

6 BY MS. SHORES:

7 Q. Dr. Levy, you're not an expert in cholesterol
8 metabolism, right?

9 A. Right.

10 Q. And you're not representing that you're an
11 expert in the specific area of lipid metabolism and
12 drugs that affect it, correct?

13 A. Correct.

14 Q. And you can't say what's generally accepted in
15 the scientific community regarding the side effect --
16 regarding the effect of niacin on blood lipids, right?

17 A. No, I don't think that's true.

18 Q. You should have a binder in front of you. Does
19 it say cross examination or something?

20 A. Yes, ma'am.

21 Q. I believe your deposition is in there, if you
22 could turn to page 191.

23 A. In my deposition?

24 Q. Yes, sir.

25 A. Okay.

1 Q. Have you got 191?

2 A. I believe so, yes, Ms. Shores.

3 Q. About halfway down.

4 A. Okay.

5 Q. And I'll read from it.

6 "QUESTION: Sir, is it generally accepted in
7 the scientific community that the effects of niacin on
8 blood lipids reduce the incidence of coronary artery
9 disease?

10 "ANSWER: I can't say what's generally
11 accepted."

12 Did you give that testimony, sir?

13 A. Yes, I did.

14 Q. Thank you. And you're not holding yourself out
15 today as an expert in that area, are you, sir?

16 A. I'm sorry, what area is that?

17 Q. What's generally accepted in the scientific
18 community regarding the effect of niacin on blood
19 lipids.

20 A. I'm not uncomfortable testifying to what I
21 perceive to be generally accepted in the scientific
22 community about that subject, so I don't think I would
23 say yes to your question.

24 Q. Okay. So, something's changed between now and
25 your deposition. Is that what your testimony is?

1 A. I don't think so, no.

2 Q. Okay. Now, sir, you are representing that
3 you're an expert on the state of knowledge in the
4 pharmaceutical industry in 1997 on sustained release
5 niacins. Is that correct?

6 A. I'm sorry, I'm just trying to think of -- you
7 know, to answer your question. I -- am I an expert on
8 the state of knowledge within the pharmaceutical
9 industry on sustained release niacins?

10 Q. Right.

11 A. I think the answer to that is yes and no
12 depending on how you interpret that question.

13 Q. Well, I'll ask it again. I thought it was
14 pretty clear.

15 My question is whether you're here today
16 testifying as an expert on the state of knowledge in
17 the industry in 1997 on the topic of sustained release
18 niacin.

19 A. Yes, I mean, I'm conscious of the fact that I,
20 you know, don't -- I'm not as responsive as I think I'm
21 being to some of your questions, and the reason I am
22 saying what I'm saying is that I don't -- I believe
23 that I am aware of what other people had said and had
24 written about this matter, and so if that's what you're
25 asking me, I think I am qualified and I am, if you

1 will, an expert on what other people have written and
2 said about it.

3 If you're asking me am I one of those experts,
4 then I'd say no, I'm not, and that's where I'm
5 confused.

6 Q. Okay, I think I understand. So, you're saying
7 that you're not an expert on sustained release niacins
8 in the time frame of 1997, but --

9 A. Again, I have to say --

10 Q. -- you are an expert on what other experts were
11 saying on that topic. Is that right?

12 A. That's fair to say, yes.

13 Q. Now, you were asked about -- I think you've got
14 your -- you may not, but your direct examination
15 booklet. You were asked about an article, do you
16 remember that, on direct examination?

17 A. This morning?

18 Q. Yes.

19 A. Yes, I do.

20 Q. And have you got that sir?

21 A. I believe so, someplace here.

22 Q. That's SPX 613.

23 A. Let me see where that is. Yes, I have it.

24 Q. Now, sir, isn't this -- wasn't this article
25 published in 1998?

1 A. Yes.

2 Q. Okay. So, nobody had the benefit of this
3 article in 1997, did they?

4 A. That's correct.

5 Q. Okay. And Schering certainly -- there was no
6 way for Schering to have read this article in 1997 when
7 it was considering Niacor, correct?

8 A. Correct.

9 Q. All right. So, let's turn to some articles
10 that were written as of 1997.

11 A. Okay.

12 Q. Okay? If you could turn to CX 540, and this is
13 in the binder I gave you.

14 A. Okay. I'm sorry, would you repeat the number,
15 please?

16 Q. CX 540.

17 A. These are labeled differently.

18 Q. It should be towards the -- after you -- past
19 your deposition and testimony.

20 MR. CURRAN: Back in the cross binder, correct?

21 THE WITNESS: Oh, 540?

22 BY MS. SHORES:

23 Q. CX 540.

24 A. I've got it, okay.

25 Q. Do you recognize this, sir?

1 JUDGE CHAPPELL: Mr. Curran?

2 MR. CURRAN: I have it, Your Honor, thank you.

3 I was attempting to be helpful, thank you.

4 JUDGE CHAPPELL: Thank you.

5 THE WITNESS: This is that memo, okay.

6 JUDGE CHAPPELL: I'm sorry if I thought you
7 were lost. I didn't know you were trying to be
8 helpful.

9 MR. CURRAN: Perhaps it's out of character.

10 BY MS. SHORES:

11 Q. You've seen that before, right?

12 A. I believe so, Ms. Shores.

13 Q. Just to refresh you, see if this helps, this is
14 what Schering had obtained from Kos with respect to
15 Niaspan when Schering was evaluating Niaspan. Does
16 that ring a bell?

17 A. Yes, it does.

18 Q. And you might recall that there was some draft
19 labeling and some materials from Kos' prospectus in
20 those materials. Does that ring a bell?

21 A. Yes.

22 Q. Now, there was also, as you can see from the
23 bullets here, a reprint of the first clinical
24 publication on Niaspan. Do you see that?

25 A. In the bullet -- yes, I see that.

1 Q. Do you see where that's referenced on CX 540?

2 A. Yes.

3 Q. Okay. Now, can you tell us who wrote that
4 article? Let me just ask you without you looking at
5 it, and we will look at it if we need to, but can you
6 tell us who wrote that article?

7 A. I don't recall.

8 Q. You don't recall. And can you tell us anything
9 about the study that was referred to in that article?

10 A. I honestly -- I don't remember what that --
11 what that study -- what study you're referring to in
12 this -- in this article.

13 Q. Okay. So, you couldn't tell us, you know, how
14 many patients were included in the trial, anything like
15 that, right?

16 A. How many patients were included in the Niaspan
17 trial?

18 Q. Yeah. And again, I -- this is the information
19 that Schering had at the time that it was evaluating
20 Niacor, and part of that was an article that it had
21 gotten from Kos. Are you with me?

22 A. Right.

23 Q. Okay.

24 A. Well, no, that's really -- I don't know how to
25 answer that question, because that was not in the -- in

1 the binder of material that Mr. Audibert said he relied
2 on in his review of Niacor. So, I'm not sure what
3 you're asking me.

4 Q. So, in giving your testimony on what Schering
5 knew with respect to sustained release niacins
6 generally, you didn't consider what it had received
7 from Kos.

8 A. Well, that's a different question.

9 Q. I'm asking it.

10 A. Well, I'm -- would you please ask me the
11 question again so I know what I'm answering?

12 Q. Sure.

13 Will you read it back?

14 (The record was read as follows:)

15 "QUESTION: So, in giving your testimony on
16 what Schering knew with respect to sustained release
17 niacins generally, you didn't consider what it had
18 received from Kos."

19 THE WITNESS: No, I'm not saying that at all.

20 BY MS. SHORES:

21 Q. Well, that's one of the things you testified
22 about here today, right, was what Schering knew on the
23 topic of what was known in the industry generally about
24 sustained release niacins?

25 A. Yes.

1 Q. Okay. And in forming your opinion, your expert
2 opinion on that issue, did you consider the article
3 that is attached to CX 540 --

4 A. Yes.

5 Q. -- on the issue of sustained release niacin?
6 So, you reviewed that?

7 A. I don't know if -- I mean, you haven't let me
8 look at this article yet, so I don't know if I've
9 reviewed it or not, but I'm familiar with Kos and with
10 Niaspan, and as I believe I testified this morning,
11 that Niaspan was the exception to the rule. So, I
12 said -- I mean, I think if I didn't say it this
13 morning, I certainly -- my -- the interpretation of
14 what I said is that all the other sustained release
15 niacins had been toxic and that Niaspan was the
16 exception to the rule, and that wasn't -- one doesn't
17 generalize from the exception. One generalizes from
18 the rule.

19 Q. I heard that when you said it earlier.

20 A. Okay.

21 Q. My question is whether in considering what
22 Schering knew about sustained release niacins
23 generally, did you consider the fact that it had in its
24 possession this article?

25 A. As I said, I don't know what this article is,

1 so I can't answer that.

2 Q. Okay.

3 A. But I'm -- I'm saying that I knew they knew
4 about Niaspan. I don't know about this particular
5 article.

6 Q. Okay. Well, let's go to -- at the bottom on
7 the right, it's 2805.

8 A. Is this the article you're going to let me look
9 at now?

10 Q. Yep.

11 A. Okay. I'm sorry, 28?

12 Q. 2805.

13 A. 2805. Okay.

14 Q. It's an article by a Dr. Morgan?

15 A. Yes.

16 Q. Do you see that?

17 A. Um-hum.

18 Q. It's called, "Treatment Effect of Niaspan, a
19 Controlled-Release Niacin, in Patients With
20 Hypercholesterolemia, a Placebo-Controlled Trial."

21 Do you see that?

22 A. Yes.

23 Q. Now, in forming your opinion about what
24 Schering knew with respect to sustained release niacins
25 generally in the industry, did you consider this

1 article, now that you've had a chance to look at it?

2 A. I don't recall. I don't recall whether I read
3 this article or not.

4 Q. Okay. So, I take it you couldn't sitting here
5 today tell us how many patients were tested in that
6 study?

7 A. Without refreshing my memory or looking at it,
8 no.

9 Q. Okay. All right, well, maybe Seth will give
10 you a chance to do that.

11 If you could turn to the last page of this
12 exhibit --

13 A. Of this article?

14 Q. Yes, sir.

15 A. Okay.

16 Q. This references a whole bunch of other
17 articles, many of which are on the topic of sustained
18 release niacins.

19 A. Yes, yes.

20 Q. Is that fair to say?

21 A. I haven't perused this list, but if you'd like
22 me to, I will do that.

23 Q. Well, yeah, why don't you do that, sir. And
24 again, my question is whether many of these articles
25 that are referred to here are on the topic of sustained

1 release niacins.

2 A. (Document review.) Just -- just superficially
3 perusing the titles of these articles, out of the 32
4 citations, it looks like something like six to eight of
5 them at least have in the title some mention of
6 controlled release or sustained release or something
7 niacin.

8 Q. Fair enough.

9 All right, Dr. Levy, I'd like to focus your
10 attention on -- let's start out with the article that's
11 referenced in note 13. Do you see that, sir?

12 A. Yes, I do.

13 Q. That's an article authored by an individual
14 named Keenan and some other folks. The title is,
15 "Niacin Revisited: A Randomized Controlled Trial of
16 Wax-Matrix Sustained-Release Niacin in
17 Hypercholesterolemia."

18 Have I got that right?

19 A. Yes.

20 Q. I take it you reviewed that article.

21 A. I think I actually did, back in -- because I
22 did a MedLine search myself on this subject way back
23 when. You know, this was a while ago, and I think that
24 particular one I did -- it -- the Keenan author sounds
25 familiar.

1 Q. Okay. So, I take it you can tell us what's
2 generally contained in that article?

3 A. I would rather not do that without refreshing
4 myself. I read it months ago.

5 Q. Well, can you at least tell us what the
6 sustained release niacin was that was tested in that
7 article?

8 A. I'd rather not guess.

9 Q. So, you don't know?

10 A. I -- I don't know whether I know or not, and I
11 don't see any purpose in my guessing when -- when if
12 you want me to look it up, I'll be happy to look it up.

13 Q. You can't recall -- you think you read it --
14 are you sure you read it or you think you read it?

15 A. I think I read it.

16 Q. You think you read it, all right, but in any
17 event, you can't recall what the niacin product was
18 that was tested in there. Is that right?

19 A. I don't know whether I recall or not. I don't
20 see any point in being inaccurate about it.

21 Q. Well, not to get too technical, but sitting
22 here today, you don't recall, right? Right now, you
23 can't tell us?

24 A. I don't recall enough that I want to venture a
25 guess in a courtroom.

1 Q. Okay. And I take it your testimony would be
2 the same with respect to the number of patients that
3 were treated and what the effects of the niacin product
4 that was tested were.

5 A. In this particular article?

6 Q. Yeah.

7 A. That's correct.

8 Q. Okay. And so you couldn't tell us, sir, the
9 percentage of patients in the trial that was reported
10 in that article who were treated with a sustained
11 release niacin who developed elevated liver enzymes?

12 A. Yes, that's correct.

13 Q. And the same would go for the percentage of
14 patients who received placebo in that trial who
15 reported elevated liver enzymes?

16 A. That's correct.

17 Q. All right, let's go back again to these end
18 notes.

19 A. To what?

20 Q. Have you got them there? The notes in CX 540.

21 A. Okay.

22 Q. Note 14 references an article by an individual
23 named Knopp entitled, "Contrasting Effects of
24 Unmodified and Time-Release Forms of Niacin on
25 Lipoproteins in Hyperlipidemic Subjects: Clues to

1 Mechanism of Action of Niacin."

2 Do you see that, sir?

3 A. Yes.

4 Q. And that's an article that was reported in a
5 journal called Metabolism. Is that right?

6 A. That's correct.

7 Q. 1985?

8 A. Yes.

9 Q. Can you tell us about that article?

10 A. Yes, I'm afraid -- I mean, as I said before, I
11 remember very well doing a MedLine search, and I
12 specifically used as a search, you know, search words
13 niacin, sustained release niacin, et cetera, and this
14 came up as well. I believe this article I could not
15 get the full text article. All I was able to read was
16 the abstract on that article, because --

17 Q. Sir --

18 A. -- because from MedLine you can just get the
19 abstracts, and then you have to go to the library or
20 whatever, and the library that was close enough to me
21 didn't have Metabolism, so I didn't read that article.

22 Q. Okay. So, you couldn't tell us what was stated
23 in that article, right?

24 A. I believe -- I read probably 20 or more
25 articles in this general area back in the fall, and

1 they all, I must confess, have become a bit of an
2 amalgam in my mind, and I can't remember what was in
3 each one, and I think that's -- I mean, that's all --
4 that's the best I can do without refreshing my own
5 memory.

6 Q. Okay. So, you can't tell us specifically
7 anything about any of the articles in here on sustained
8 release niacin products. Is that right?

9 A. Well, I haven't --

10 Q. And let me just give you an example.

11 A. On those two, no. I'm sorry, I don't know
12 about the others. We haven't gotten to them.

13 Q. Well, why don't you take a look at the six that
14 you identified or whatever and tell me whether you can
15 tell me anything about the studies that were reported
16 in those articles.

17 A. Okay. (Document review.) I mean, I can -- I
18 mean, I can abbreviate this exercise and say that I
19 would be uncomfortable testifying to the details of any
20 article I read probably on any subject three months
21 after I read it without refreshing my memory. So, I
22 can't -- I can't testify. If you're going to ask me
23 how many patients were in this trial and how many --
24 what the percentages were and so on, I think it would
25 be unwise of me to try to guess what my recollection is

1 when I know that those kind of things are available if
2 I have to know what the information is.

3 Q. Okay. So, let me see if I understand what
4 you're testifying to today then. You can't tell us any
5 details from these publications, these published
6 reports on sustained release niacin products. You're
7 just here offering some sort of general opinion about
8 what the state of knowledge was in the industry in
9 1997?

10 A. I'm not sure I'd be quite that pejorative of
11 what I'm saying.

12 Q. I don't mean to be pejorative. I'm just trying
13 to understand whether you have any specific knowledge
14 or whether you're just offering a general opinion.

15 A. I think specific knowledge about -- specific
16 opinions about the other sustained release products
17 where the opinion, as I recall it, was consistent, that
18 these products had GI and hepatotoxic problems, and I
19 don't remember what particular authors said what and
20 how he came to those conclusions. I think -- because
21 that's what I think you're asking me, is an overall
22 opinion of being familiar with the literature, not any
23 particular component of the literature.

24 Q. Okay. Well, let's -- first of all, can you
25 tell us, sir, the names of some of the other sustained

1 release niacin products that were out there in 1997?

2 A. No. In fact, most of them didn't really have
3 names, because they never made it to the marketplace.

4 Q. Weren't some sold over the counter, sir?

5 A. Yes, but I don't recall the names.

6 Q. How about giving me the names of those?

7 A. I don't recall their names. There is a
8 Slo-Niacin I think is one name, and I don't recall --
9 but other than that, I don't really recall the others.
10 There's also a -- there's a -- some of these articles,
11 if I remember correctly, were a pro drug of niacin, not
12 really a sustained release niacin. It was a form of
13 nicotinamide, you know, isosorbide, you know, that is
14 sort of a sustained release formulation. It's sort of
15 a sustained release niacin but not -- not -- it's a
16 sustained release mechanism that's a chemical sustained
17 release as opposed to a formulation sustained release.

18 Q. Okay. Well, other than Slo-Niacin, can you
19 name any other sustained release niacin products?

20 A. Well, what I just said, the isosorbide
21 nicotinamide.

22 Q. So, that's two?

23 A. Yes.

24 Q. Can you name any others?

25 A. No.

1 Q. All right, I'm going to switch topics on you.

2 Dr. Levy, if a physician is treating somebody
3 with a sustained release niacin, okay?

4 A. Um-hum.

5 Q. The physician wouldn't start with a 2000
6 milligram dosage, would he?

7 A. Generally not.

8 Q. He would titrate or -- I don't know how to
9 pronounce that, but he would do that upwards until he
10 got to 2000, right?

11 MR. SILBER: Your Honor, objection. I don't
12 know how this responds in any way to what he went
13 through on direct. This is outside the scope of his
14 direct.

15 JUDGE CHAPPELL: I'm going to allow some leeway
16 here. There were a number of objections on direct, and
17 based on Rule 705, I instructed the respondents that
18 all the underlying data and assumptions supporting the
19 opinions of the witness did not have to be revealed on
20 direct, but they could inquire on cross. So, I'm going
21 to allow it. Overruled.

22 MR. SILBER: Thank you, Your Honor.

23 BY MS. SHORES:

24 Q. Just to orient you, I think you gave some
25 testimony on direct about people wanting -- some -- you

1 or somebody else wanting to know data about dosages
2 over 2000 milligrams. Do you remember that?

3 A. Yes.

4 Q. Okay. So, that's where I am.

5 A. Okay.

6 Q. All right?

7 Now, so, my question is, a doctor wouldn't
8 start a patient on 2000 milligrams, would he?

9 A. Not typically.

10 Q. Well, you would start with a lower dose and see
11 if that worked before you went to 2000, right?

12 A. Physicians tend to do an awful lot of different
13 things. I think you're asking me would a physician
14 generally start that way, and I think it generally not.
15 Generally -- I think that the general thing that a
16 physician does is push the dose until he gets either
17 the therapeutic effect he wants, a toxic effect that
18 causes him to stop, or to the point of the maximum
19 label amount. I mean, those are the three things, and
20 sometimes doctors, as I testified this morning, will go
21 beyond the labeled amount, you know, for the drug, I
22 mean they will just keep going until he gets an adverse
23 effect.

24 Q. Okay. And let's say if the patient started at
25 1000 milligrams and the patient achieved the efficacy

1 goal that the doctor was looking for, he wouldn't
2 increase the dose after that, would he?

3 A. There are myriad variables there, Ms. Shores.
4 I mean, he might, because, for instance, with
5 cholesterol-lowering, the subject we're talking about
6 now, it might be nice to lower the LDL by 10 percent,
7 but maybe it would be better to lower it 15 percent,
8 and so he might be getting -- he might get an effect at
9 1000, and if he thinks he can get a better effect at
10 1500, he would go farther.

11 Q. Well, if he got to 15 percent at a thousand,
12 would he go higher?

13 A. It depends where the patient started. If the
14 patient started with a 500 cholesterol and he lowers it
15 10 percent, that wouldn't be a big deal. He might want
16 to try to lower it 50 percent.

17 Q. Okay. Well, how about -- let's pick an actual
18 number goal as opposed to percentages. What's a good
19 cholesterol level?

20 A. Well, again, you know, a good doctor doesn't
21 treat on averages. He looks at each patient
22 individually, and, you know, a patient running around
23 with a 300 cholesterol and no cardiovascular problems
24 is different from a guy running around with 180
25 cholesterol who's had cardiovascular problems, and, you

1 know --

2 Q. Why don't we pick whichever one makes you more
3 comfortable.

4 A. Well, either of them would make me comfortable,
5 because as a physician I might see both. I might see
6 guys running around with quite significantly elevated
7 cholesterol, let's say 350, with no cardiovascular
8 symptoms, and let's say, if you want to --

9 Q. Let's just take that, okay?

10 A. Okay.

11 Q. Let's take this. You've got a guy running
12 around, he's got an LDL level 350 --

13 A. You're talking LDL, I was saying total
14 cholesterol, but that's fine, okay.

15 Q. I don't care, but let's say LDL. Is 350 the
16 right number to use with LDL?

17 A. That's pretty high, but go ahead.

18 Q. Okay, 350. Now, where would you want to get
19 that patient if you were treating him for high
20 cholesterol in terms of LDL?

21 A. I know you don't want this answer, but it
22 depends on the individual patient. I don't -- I'd like
23 to get him as low as I could get him safely.

24 Q. I'm trying to get there.

25 A. I understand.

1 Q. Can you pick a number hypothetically that you'd
2 be trying to get him to?

3 A. 110.

4 Q. 110, okay. And let's say -- it's hypothetical,
5 okay -- let's say you decided to try first a sustained
6 release niacin product.

7 A. Okay.

8 Q. Okay.

9 A. Single agent sustained release niacin.

10 Q. Yep.

11 A. Okay.

12 Q. And let's say you start him on 1000
13 milligrams --

14 A. Okay.

15 Q. -- just to see what that would do.

16 A. Right.

17 Q. And lo and behold, he came back and his
18 cholesterol had dropped from 350 to 110, okay?

19 A. Um-hum.

20 Q. You wouldn't increase the dosage of sustained
21 release niacin, would you?

22 A. No.

23 Q. Thank you.

24 I'm going to switch topics again. I want to
25 talk a little bit about Vasomax.

1 A. Okay.

2 Q. You raised that in your direct testimony. Is
3 that right?

4 A. I think so.

5 Q. Or Mr. Silber did, I should say.

6 A. Yes.

7 Q. And you were talking about what studies were
8 required in Europe based on a document for Vasomax to
9 get approval, right?

10 A. Okay. I mean, I don't think we talked -- we
11 never got to the point of talking about specific
12 studies, so that's why I'm trying to be accurate.

13 Q. Well, let me just ask you this: Vasomax is not
14 the same thing as Niacor, is it?

15 A. No.

16 Q. It's not a niacin product, right?

17 A. No.

18 Q. And it's not even a sustained release product,
19 right?

20 A. Well, actually, it's -- no, it's -- I don't
21 want to mince words with you. No.

22 Q. In fact, it's an immediate release product.

23 A. Yeah, I mean the reason I hesitated for a
24 moment, it does share with Niacor the fact that one of
25 its elements is altering the pharmacokinetics, if you

1 will, you know, of a -- of another drug, and so they do
2 share that. One -- one is speeding it up and the other
3 is slowing it down, but...

4 Q. Okay, but in this sense, it's really the
5 opposite. I mean, a sustained release would be the
6 opposite of immediate release, right?

7 A. No, that's right, I agree.

8 Q. I'm going to pass some more stuff out.

9 A. I'm sorry?

10 Q. I'm going to pass some more binders out.

11 A. Can I give you this one back?

12 Q. Well, the trouble with that is it's got your
13 testimony in it.

14 A. Can I trouble you to take these away?

15 Q. Sure. Why don't we put them up here, just in
16 case we need to refer to something in there.

17 A. Okay.

18 Q. Okay, I'm now going to address that portion of
19 your testimony that had to do with noncontingent
20 payments versus other sorts of payments.

21 A. Okay.

22 Q. Okay? First of all, let me just see if we can
23 get an understanding as to what you mean by
24 "noncontingent payment."

25 A. A noncontingent payment is a payment you have

1 to make regardless of what else happens.

2 Q. So, it would be, you know, a sunk cost that you
3 would have to pay no matter -- even if everything went
4 wrong.

5 A. Yes.

6 Q. Okay. And so I think your testimony was you
7 regard anticipated research and development
8 expenditures as something totally different.

9 A. Yes.

10 Q. And I take it for the same reason you wouldn't
11 put milestones in the same category as noncontingent
12 payments, right?

13 A. Yes.

14 Q. You would not.

15 A. They're different.

16 Q. Okay.

17 A. I'm not -- I don't want to get caught in the
18 negatives here.

19 Q. Now, the same goes for purchases of equity as
20 distinguished from cash up-front payments except in the
21 case where you're buying the equity at a premium.
22 Isn't that what you said --

23 MR. SILBER: Objection, Your Honor. We did not
24 discuss equity payments in any way during his direct.

25 MS. SHORES: Your Honor, he's testified that

1 noncontingent up-front payments are different from all
2 other sorts of licensing payments, and I think I'm
3 entitled to explore with him other licensing payments.

4 MR. SILBER: Your Honor, this was an issue that
5 was addressed in the case in chief in his testimony.
6 It was not addressed in his rebuttal testimony.

7 JUDGE CHAPPELL: Did he testify to this today?

8 MS. SHORES: Well, I think he -- he was at
9 pains to distinguish an up-front cash payment as being
10 different from other sorts of payments that one might
11 make when entering into a licensing transaction.

12 JUDGE CHAPPELL: He said that today?

13 MS. SHORES: Yes, sir.

14 JUDGE CHAPPELL: Why don't you ask him about
15 that. Objection sustained.

16 BY MS. SHORES:

17 Q. You said that, right?

18 A. I don't recall saying anything about that, but
19 I'm -- you know...

20 Q. Well, you remember that you went over Mr.
21 Lauda's chart, right?

22 A. Yes.

23 Q. And he had put some stuff on top of what you
24 had earlier pointed out were noncontingent cash
25 payments, right?

1 A. Yes.

2 Q. Okay. And you testified, right, that \$60
3 million was the largest payment Schering had ever made
4 up front, right?

5 A. Yes.

6 Q. And in fact, I think you testified that \$60
7 million was the largest up-front licensing fee ever in
8 the history of the industry.

9 A. Cash licensing.

10 Q. Cash licensing fee, right?

11 A. Yes.

12 Q. Okay. So, I want to talk about non-cash
13 licensing fees. Are you with me?

14 A. Yes. I didn't talk about that. If you want --
15 I mean, I --

16 Q. Well, I am going to ask you about it.

17 A. Okay.

18 Q. Okay? Because again, you've taken the position
19 that cash is different from this other stuff, so I'm
20 going to ask you about the other stuff.

21 A. Okay.

22 Q. Okay?

23 A. Again, I don't know -- I don't know what the
24 rules are, and I didn't talk about that this morning,
25 if that's what you're asking me.

1 Q. Well, let me just ask the question.

2 You've testified that you wouldn't put
3 anticipated R&D expenses in the same category as cash
4 up front, right?

5 A. Yes.

6 Q. And the same is true, sir, is it not, for
7 equity purchases that are at a premium, right?

8 A. Right, what? I'm not sure what you're asking
9 me.

10 Q. It's not the same as cash up front according to
11 you.

12 A. Yes, but for a different reason.

13 Q. Okay, but -- well, let's explore that. I mean,
14 one of the reasons is, right, that you think having
15 equity gives the company some -- who was purchasing it
16 some control?

17 A. No, it's -- it's a different matter. When you
18 get -- this is not something I talked about today.
19 This is something I talked about I believe in my
20 original direct testimony.

21 Q. Well, let me ask you this: Would you -- and
22 for purposes of comparing the Schering up-front payment
23 to other payments -- I mean other licensing deals,
24 either that Schering did or that were done in the
25 industry generally, did you compare just the up-front

1 cash portion across deals or did you also include
2 equity when it was bought in other deals?

3 A. I'm sorry to be so confused by what you're
4 asking me. I don't want to answer your question
5 improperly.

6 Q. Let me try it again.

7 You said that \$60 million was the largest
8 up-front licensing fee ever, right?

9 A. The largest up-front cash licensing fee ever.

10 Q. Right. And so you don't consider a purchase of
11 equity in the same category as cash.

12 A. That's correct.

13 Q. Thank you.

14 And you also don't think it's fair to compare
15 co-promotion agreements with licensing agreements,
16 right?

17 A. Correct.

18 Q. And I take it you would also exclude from your
19 comparative database deals in which the party trying to
20 acquire the product bought the whole company.

21 A. That really has not been discussed in any of my
22 testimony, I don't believe. I don't think that any --

23 Q. I'm just asking you -- I'm asking you a
24 question. Would you exclude that -- when you're --
25 when you make your statement that \$60 million was the

1 largest up-front fee, are you excluding deals for
2 comparative purposes in which the party seeking the
3 product bought the whole company?

4 A. Well, sure. I mean, if you buy the whole
5 company, you're not buying a product.

6 Q. Well, sometimes a company just has one product,
7 right? That happens, right, with small companies, and
8 big pharmaceutical companies buy the whole company just
9 to get the product?

10 A. Well, now you're making the assumption of why
11 they've done it, and I'm not willing to agree to that.

12 Q. So, you don't think that that happens in the
13 industry?

14 A. Companies buy whole companies that have a
15 single product, that I'll agree to, and I will also
16 agree that buying a whole company is different from
17 licensing an individual product.

18 Q. Okay.

19 A. What I'm not agreeing with is that all the
20 company gets when it buys another company is the
21 product, because it gets all the infrastructure of that
22 company, it gets the sales force, it gets whatever
23 they've got in addition to just a license to a product.

24 Q. Okay. Now, again, why don't you just tell us
25 why it is that you isolate the cash up-front fee from

1 other sorts of fees for purposes of comparing the
2 Niacor deal to other deals in the industry.

3 A. Because I was trying to compare comparable
4 matters. If -- if the situation had been Schering had
5 purchased Upsher-Smith, then it wouldn't have been
6 appropriate for me to have compared the purchase of
7 Upsher-Smith to the licensing of Vasomax. I would have
8 had to have compared it to some other corporate
9 isolation. So, I'm just simply trying to be as precise
10 as I could be in comparing parameter to parameter.

11 Q. Okay. You reviewed Mr. Lauda's testimony
12 before testifying today, his trial testimony?

13 A. Yes.

14 Q. And so you're aware that he testified that he
15 at Schering -- he and Schering, when they're evaluating
16 a deal, they look at the total deal value? Do you
17 recall him testifying to that?

18 A. Yes, I do.

19 Q. And that what Schering considers is not only
20 the cash up-front fee but also all of the payments that
21 Schering would have to make before the product comes to
22 market. Do you recall him testifying to that?

23 A. Yes, I do.

24 Q. And I take it you disagree with that.

25 A. No, I don't.

1 Q. Well, so, you think that people do look at
2 total deal value and not just at cash up-front
3 licensing fee when making the determination whether to
4 enter into a license?

5 A. I agree with that.

6 Q. All right. Now, let's turn to this issue of
7 whether or not the Niacor deal was the largest up-front
8 licensing fee any company has ever paid for any drug.
9 That's what you said, right?

10 A. Prior to 1997 or prior to this deal. We're not
11 talking about what happened after this deal.

12 Q. So, you want to cut it off right at 1997 -- May
13 1997 -- June 1997?

14 A. What I testified, Ms. Shores, was that up to
15 the time of this deal, this was the largest licensing
16 fee that had ever been paid.

17 Q. That any company had ever paid for any drug,
18 right?

19 A. Up to this time, yes.

20 Q. That's a pretty bold statement nonetheless,
21 isn't it?

22 A. Quite candidly, when I entered this whole, you
23 know, investigation and when I had the opportunity to
24 look at what your side's experts had produced, I was
25 frankly surprised that they couldn't dredge up

1 something from somewhere, and they didn't. So --

2 Q. Okay.

3 A. -- I stand by my statement.

4 Q. Let's go. Now, you recall when I asked you
5 about the Procter & Gamble Regeneron deal when you were
6 here before. Do you recall that?

7 A. I don't recall your asking me about that, no.

8 Q. All right, let me see if I can dig that up.
9 You've got the binder with your deposition in it?

10 A. My deposition?

11 Q. Yes, sir.

12 A. I don't think you asked me about that in my
13 deposition, did you?

14 Q. I'm sorry, not your deposition, your testimony.
15 This was on cross examination, so it's February 5th.

16 A. Where is that?

17 Q. In the binder I gave you, binder one.

18 A. Binder one, okay. Okay, I'm -- where in --

19 Q. Let's go to page 1896.

20 A. In what?

21 Q. In the February 5th --

22 A. February 5th, okay. I'm sorry, what was the
23 page?

24 Q. It was 1896.

25 A. Okay.

1 Q. Do you see there where you're testifying
2 about -- and I'm asking you questions about the
3 Regeneron deal?

4 A. I'm not sure -- on 1896? I'm not sure what
5 you're asking me there.

6 Q. Look at 1895.

7 A. Okay. I see Procter & Gamble and Regeneron. I
8 don't know, okay.

9 Q. Does that refresh your recollection about
10 whether I asked you about that deal when you were here
11 before?

12 A. No, I do recall that you asked me about it the
13 last time --

14 Q. Oh, I thought you said you didn't. That's why
15 we went through this.

16 Now, that was a deal that was in May of 1997,
17 right?

18 A. I don't recall.

19 Q. It's a good thing we got this out.

20 Do you see that on 1895?

21 A. Yes.

22 Q. I asked you this before. It says:

23 "QUESTION: That was in May of 1997?

24 "ANSWER: Yes."

25 Do you see that?

1 A. Yes, okay.

2 Q. I take it that testimony was true, right?

3 A. Yes.

4 Q. Okay. Now, that was a deal in which Procter &
5 Gamble paid \$60 million to get the product, wasn't it?

6 A. I don't recall the details of that deal. Now,
7 at the time -- in preparation for my own direct
8 testimony, Ms. Shores, I made it a point of reviewing
9 some of these things, because I anticipated that you
10 might ask me about them, and I don't recall at this
11 point those details.

12 Q. Well, in preparing for your testimony today in
13 which you stated that this was the biggest up-front
14 licensing fee that any company had ever paid in the
15 history of the pharmaceutical industry up until June of
16 1997, did you think I might ask you questions about
17 that?

18 A. I really -- I didn't -- I frankly didn't
19 anticipate any of the questions you're -- you were
20 going to ask me today. I really didn't know what was
21 going to happen. When I made the statement this
22 morning, I was conscious of making it, and I don't
23 recall anything, including this, that in any way
24 negates that statement.

25 Q. Well, can you tell us what the terms of that

1 deal were?

2 A. That's what I'm saying, I -- unfortunately -- I
3 wish I could tell you those terms. What I will say --
4 what I am quite comfortable in saying to you is that it
5 in no way negates what I've said this morning. There
6 may be some nuance to what, you know, you're trying to,
7 you know, to create here that -- that says otherwise,
8 but I can assure you that nothing that I saw, including
9 this deal, negates that statement.

10 Q. Well, without knowing what the terms of the
11 deal were, how can you make that representation?

12 A. Because if I had seen an exception to what I
13 was saying, I would remember it, and I wouldn't have
14 made the statement. I have not seen any exception to
15 that statement.

16 Now, if you'll -- if you would like me to
17 re-review that deal, I'll be happy to do that and
18 comment further. I am quite confident that nothing in
19 this deal or any of the other deals in any way, you
20 know, contradicts the statement I made this morning.
21 Now, you're asking me for specifics of why this deal
22 doesn't, and I don't remember.

23 Q. All right, well, let's take a look at SPX 1318.
24 I believe it's in the other binder.

25 A. I'm sorry, what was the number again -- 1318?

1 Q. 1318.

2 A. Okay.

3 Q. Do you have that?

4 A. Yes, I do.

5 Q. If you could turn to the fourth page of that,
6 there's some numbers on the top right.

7 A. The fourth page? Okay.

8 Q. Okay. There's a discussion there of the
9 Procter & Gamble Regeneron deal. Is that right?

10 A. Yes. I have not seen this article before, so I
11 don't know, but I just see P&G and Regeneron in this
12 first paragraph, so I presume that's what it's about.

13 Q. Now, this is a document from a magazine
14 entitled Signals Magazine. Have you heard of that?

15 A. Yes, I have.

16 Q. What is Signals Magazine, sir?

17 A. I really don't know. I mean, I've heard of it,
18 that's what you asked me. I don't know what it is.

19 Q. Let me ask you another question. What database
20 of licensing deals did you look at in forming your
21 opinion?

22 A. The ReCap Database, there's a Windhover
23 Database and then Licensing Executives Society updates.
24 I also read The Pink Sheet and Script pretty regularly,
25 so I follow that stuff myself. Almost any deal that

1 gets done is described in The Pink Sheet usually and
2 Script, and I read those things. I subscribe to them
3 and read them pretty regularly.

4 The other publication that I relied upon was
5 another, you know, quite widely read industry
6 publication called MedAd News, whose name is a little
7 misleading, because it's really not much about
8 advertising.

9 Q. And the Recap Database, is that Recombinant
10 Capital?

11 A. Yes, I think that's what it stands for.

12 Q. And do you know whether Signal Magazine has
13 anything to do with Recombinant Capital's database?

14 A. I just don't know what Signals Magazine is. I
15 don't get it. I don't think I've ever seen a copy of
16 it to tell you the truth.

17 Q. There's another database called the Windhover
18 Database.

19 A. Yes.

20 Q. And I take it that as well as all of these
21 other sources that you just described are something
22 that someone in your business who is interested in
23 looking at licensing deals would consider?

24 A. Yeah, I mean, frankly, both the ReCap Database
25 and the Windhover Database are -- I want to say sort

1 of -- I don't want to say rough approximations, but
2 they're based on trying to glean from a variety of
3 documents what the terms of agreements are, you know,
4 and I think we -- you know, some of my earlier
5 testimony showed that there were inaccuracies in those
6 databases, because, you know, when you get the
7 opportunity to look at the real agreement, as I did,
8 for instance, in this matter, one can see that there
9 are differences between those databases.

10 They often rely, for instance, on -- because so
11 much of the -- so much of the time they can't get the
12 agreement, they can only get press releases on the
13 agreement. Press releases don't tend to be quite as
14 informative. So, it -- any opinions you form about
15 this stuff really has to come from an amalgam of
16 your -- of all the information you have. You know,
17 sometimes you can be fortunate enough to have direct
18 information, actually see the agreement; other times,
19 you have to rely on this more indirect information.

20 Q. But again, for whatever these databases
21 contain, whether they be full information or partial
22 information, that's something that somebody in your
23 position would look at. Is that correct? I mean, you
24 looked at the ReCap Database, right?

25 A. Yes, I did.

1 Q. And so I take it the Windhover Database is like
2 the ReCap Database, isn't it?

3 A. Well, again, it's not like it. Again, I'm so
4 sensitive to His Honor's not wanting my long-winded
5 answers that I'm trying to be succinct. They're
6 different. I mean, if you want to ask me how they're
7 different, you know, they cover different areas of the
8 industry, and one focuses on biotechnology, the other
9 focuses more on more traditional pharmaceutical deals,
10 and they frankly miss a lot, but, you know, there's a
11 little bit of overlap between them.

12 Q. They both miss a lot, don't they?

13 A. I don't know what "a lot" means, Ms. Shores.
14 You know, I -- when I looked through the databases just
15 for this trial, which is the only time I've really had
16 occasion to be particularly critical about those
17 databases, I didn't think that they -- they missed a
18 heck of a lot that I otherwise knew. They were off on
19 some of the details of the agreements where I knew the
20 details of the agreement.

21 Q. Sir, in forming your opinion that this was the
22 largest up-front licensing fee that had ever been paid
23 in the industry, is it your testimony, sir, that you
24 reviewed every other licensing deal in the industry?

25 A. I don't think I said that. I mean, where

1 that --

2 Q. I'm just asking you a new question.

3 A. The answer is no.

4 Q. So, you can't say that this was the largest
5 up-front payment that was ever made in the history of
6 the industry.

7 A. I probably can.

8 Q. You probably can't?

9 A. I probably can.

10 Q. You probably can?

11 A. Yes, because I mean your question was whether I
12 had reviewed every deal, and I'm sure there's some
13 \$200,000 deal somewhere that I didn't see, but a deal
14 this big doesn't get missed by Script and doesn't get
15 missed by The Pink Sheet and doesn't get missed by
16 Windhover and doesn't get missed by ReCap. You know,
17 some little dippy deal for \$100,000 might get missed.
18 This one doesn't get missed, and a deal bigger than
19 this doesn't get missed.

20 Q. Are you telling us, sir, that the entire
21 licensing agreement is reported in Script?

22 A. No, that's not what I'm saying.

23 Q. All right, so let me ask the question again.

24 Is it your testimony, sir, that you reviewed
25 every licensing deal in the industry in order to form

1 your conclusion and give your expert testimony that
2 this was the largest up-front cash payment that was
3 ever made?

4 MR. SILBER: Objection, Your Honor, asked and
5 answered. She keeps going over the same questions.

6 MS. SHORES: I'm not getting an answer, Your
7 Honor.

8 THE WITNESS: If you're asking me whether I
9 reviewed --

10 MS. SHORES: Wait, wait, wait.

11 THE WITNESS: Okay, I'm sorry.

12 JUDGE CHAPPELL: Well, it's not exactly the
13 same question, so I'll allow it. Overruled.

14 THE WITNESS: If you're asking me whether I
15 have personally reviewed every license agreement ever
16 done in the industry, the answer is no.

17 BY MS. SHORES:

18 Q. And my question is -- and this I did ask
19 before, but I got an answer that didn't make any sense,
20 so I am going to ask it again -- having not reviewed
21 every licensing deal in the industry, you can't tell us
22 whether this is the biggest up-front payment ever made
23 or not, can you?

24 A. I think that I can, yes.

25 Q. And how is that, sir, given the fact that you

1 haven't looked at every deal?

2 MR. SILBER: Objection, asked and answered,
3 Your Honor.

4 MS. SHORES: I'm just trying -- I really am
5 just perplexed, and I am trying to find out --

6 MR. SILBER: She has asked these questions
7 repeatedly and has gotten the same answer. If she's
8 still perplexed, she's gotten her answer.

9 JUDGE CHAPPELL: I am going to allow the last
10 question she asked and get his response, and then we
11 are going to move on.

12 (The record was read as follows:)

13 "QUESTION: And how is that, sir, given the
14 fact that you haven't looked at every deal?"

15 THE WITNESS: I would say that the reason I am
16 comfortable saying that is -- comes from a number of
17 areas. Number one, I am pretty familiar with what's
18 going on in our industry in general from reading
19 consistently industry publications. Number two, I did
20 consult the -- those reliable sources of deals. And
21 number three, and one which I didn't mention before but
22 I think is germane, is the fact that I reviewed
23 carefully the testimony of your experts who had a
24 distinct vested interest to find a bigger deal, and
25 your expert, Mr. Bratic, found nothing, which I was

1 frankly surprised at.

2 I thought he would be able to dredge up
3 something from somewhere, but he didn't, and so have I
4 exhaustedly reviewed everything possible? I think
5 everything reasonable.

6 MR. CURRAN: Your Honor, I move to strike the
7 reference to Mr. Bratic. Mr. Bratic didn't come to
8 testify in respondents' case in chief, and secondly,
9 Dr. Levy has completely mischaracterized Mr. Bratic's
10 conclusions.

11 JUDGE CHAPPELL: We're not going to get to the
12 mischaracterization. I'll disregard any reference to
13 Mr. Bratic who has not testified. Sustained.

14 MR. CURRAN: Thank you, Your Honor.

15 BY MS. SHORES:

16 Q. Sir, isn't it the case that part of what you
17 relied on is industry publications and not the actual
18 deals themselves?

19 A. Did you say part?

20 Q. Um-hum.

21 A. That's correct.

22 Q. So, sometimes you relied on a published news
23 article about a deal and not the deal itself, correct?

24 A. Correct.

25 Q. Okay, let's go back to where we were.

1 Again, this is from Signals Magazine, talking
2 about the Procter & Gamble Regeneron deal, and
3 according to this published report, in this deal,
4 Procter & Gamble agreed to pay \$60 million in equity at
5 a 22 percent premium. Do you see that?

6 A. Yes.

7 Q. And an additional \$75 million over five years.

8 A. I see the \$75 million, yes.

9 Q. Okay. And sir, isn't it the case that that is
10 bigger than \$60 million up front?

11 A. You're comparing apples and oranges. Is the
12 number bigger? Yes, but you conveniently left out --
13 when you said \$75 million, you left out the words in
14 FTEs.

15 Q. What does that mean?

16 A. Full-time employees, so they were paying for
17 full-time employees to do research on their behalf. I
18 don't consider that the same.

19 Q. You don't think that was noncontingent?

20 A. I can't say whether it's contingent or not
21 contingent from this. Generally when you're paying for
22 employees, it's quite contingent.

23 Q. Let's move on to another deal.

24 You're familiar, I take it, with the deal
25 between Pfizer and Searle in February of 1998?

1 A. Which deal are you referring to?

2 Q. Why don't you turn to SPX 1319.

3 A. Are you talking about the co-promotion of
4 Celebrex?

5 Q. Yep. Are you familiar with that deal, sir?

6 A. Yes.

7 Q. And in that one, Pfizer paid Searle \$85
8 million, correct?

9 A. I don't recall the details of that. I'm just
10 reading what's on the screen. I don't have any reason
11 to deny -- I just don't recall those numbers.

12 Q. Well, \$85 million is bigger than \$60 million,
13 right?

14 A. Yes, and this is an apple -- total apples and
15 oranges comparison. This is a co-promotion for one of
16 the most important breakthrough drugs in the last two
17 decades, and it's ironic that you're bringing this up
18 since this was \$85 million for a major breakthrough
19 drug co-promotion that had already been approved, and
20 you're comparing it to a \$60 million payment for a dog
21 that never made it to the -- never saw the light of
22 day. Unbelievable.

23 Q. Sir, is it usually the case that in a
24 co-promotion agreement, the party acquiring the rights
25 to the product gets less than 100 percent of the

1 profits?

2 A. The party -- I'm sorry, say that again.

3 Q. Isn't it the case in a co-promotion arrangement
4 that the party who is acquiring the rights to market
5 the product, the acquiring party --

6 A. Yes.

7 Q. -- usually gets less than 100 percent of the
8 profits?

9 A. Yes.

10 Q. You don't think there's any way to compare that
11 to a licensing deal in which the acquiring party gets
12 100 percent of the profits?

13 A. Well, first of all, the acquiring party doesn't
14 get 100 percent of the profits in a licensing deal, so
15 I'm not sure -- well, you know, don't -- don't sluff it
16 off. I mean, you are trying to put words in my mouth
17 that are incorrect, and I won't let you do that.

18 Q. Well, let me ask you this, sir: Under the
19 Niacor deal, Schering got -- except for the royalty,
20 which was, what -- do you remember what the royalty
21 payment was?

22 A. Yes.

23 Q. And what was it?

24 A. The royalty was to be 10 percent of the one
25 sales level, I believe it was \$50 million, and then 15

1 percent beyond that.

2 Q. All right. Except for the royalty payments,
3 Schering was going to get to keep all of the profits
4 from the sales that it made in the territories that it
5 licensed Niacor for, right?

6 A. Well, I mean, that is a -- that's a very
7 misleading comment, because when you say "except for
8 the royalty payments," you know, the royalties are
9 based on providing to the licensor, that is, you know,
10 the -- in this case it would have been Upsher-Smith,
11 providing to the licensor a fraction of the anticipated
12 profits, so that the licensor almost always gets a
13 piece of the anticipated profits, and so I really --

14 Q. The licensee typically gets a whole lot more,
15 doesn't it?

16 A. The licensee typically gets somewhere between,
17 oh, 55 and 75 to 80 percent of the profits, not all of
18 them.

19 Q. Let's turn to SPX 872, I believe, in that
20 binder.

21 MR. SILBER: Your Honor, if I may, I object to
22 this line of questioning. Dr. Levy offered his
23 opinion, as he's made clear, that the \$60 million was
24 the largest noncontingent payment up until the time of
25 this deal in June of 1997. These deals that Ms. Shores

1 is going through now post-date that. He did not offer
2 an opinion as to that, and in this binder she has a
3 whole host of deals that are beyond the June 1997
4 settlement, and I think this is beyond the scope of his
5 direct.

6 MS. SHORES: Your Honor, I don't understand why
7 this witness draws the line where he does. I think
8 that these are -- it's relevant to consider this deal
9 in the context of the time frame in which it was
10 entered and not to arbitrarily cut it off after June.

11 MR. CURRAN: Your Honor, if I could add in, I
12 think I have an interest in the issue as well. The
13 witness has testified that the \$60 million was greatly
14 excessive or something like that without qualification
15 as to specific time frame.

16 JUDGE CHAPPELL: Well, and as I recall -- and I
17 haven't committed his direct to memory yet from
18 today -- but I believe there were charts on the screen
19 talking about the deal, and he did talk about I think
20 the fact that it was not minimal, a minimal payment.
21 So, I'm going to allow it, but I don't think we need to
22 go into a lot of detail on these examples, Ms. Shores.

23 MS. SHORES: I'll try not to belabor it, Your
24 Honor.

25 MR. SILBER: Thank you, Your Honor.

1 BY MS. SHORES:

2 Q. Have you got SPX 872?

3 A. Yes.

4 Q. And this involves a deal between Lilly and
5 Icos. Is that right?

6 A. Yes.

7 Q. And this is the one when you were here before
8 you said you knew more about them than the Windhover
9 Database, right?

10 A. I think this is the one, yes.

11 Q. And according to the Windhover Database, it
12 says here that Lilly will pay Icos \$75 million up
13 front. Do you see that?

14 A. No, I don't see that.

15 Q. It's right on the -- it's right there
16 (indicating).

17 A. Oh, I see it, right.

18 Q. To share 50/50 North American and European
19 profits from the sale of Icos' phase II oral
20 anti-impotence drug. You're familiar with this deal,
21 right?

22 A. With what? With the deal, yes, ma'am.

23 Q. Okay. And it says Lilly has also agreed to pay
24 Icos an added \$52.5 million to form a joint venture.

25 A. I see what it says.

1 Q. And so in this deal, Lilly paid Icos \$75
2 million plus \$52.5 million.

3 A. No, that's -- that's where -- you know, this is
4 an example of where this -- this reporting of the
5 Windhover Database is a bit misleading.

6 Q. So, you don't think that's accurate?

7 A. That's correct.

8 Q. Well, you know, you said that before, so I
9 actually had the opportunity to do a little digging on
10 that, if you could turn to SPX 1320.

11 A. Okay.

12 Q. If you go to the second page, this is from an
13 SEC filing by Icos.

14 A. Yes.

15 Q. It says there, and I'm quoting from the --
16 about the fifth paragraph down, you can see it on your
17 screen, I think, "Icos and Lilly will establish a 50/50
18 owned joint venture. Icos will receive a \$75 million
19 up-front payment and success milestone payments based
20 on the progression of IC351 through development. Icos
21 and Lilly will both capitalize the joint venture
22 through a cash infusion by Lilly over a three-year
23 period and the contribution by Icos of intellectual
24 property associated with IC351 and its research
25 platform."

1 A. Yes.

2 Q. Do you see that?

3 A. I see it.

4 Q. Doesn't that indicate that the \$52.5 million
5 payment in reference to the previous exhibit was on top
6 of the \$75 million?

7 A. I didn't say it wasn't -- first -- I wish I
8 could go back and consult my notes. The -- the --
9 what's misleading about this was that, as I understand
10 this deal, and I'm doing this from memory, and I -- and
11 it's -- it's a little awkward doing that, particularly
12 when I have the absolute facts in written form that I,
13 you know, would rather consult. A joint venture was
14 formed, and the -- both Icos -- you know, a typical
15 licensing deal has the licensee doing all the research
16 after the deal is done.

17 This was different. This was a joint venture
18 where both parties were going to be developing this
19 drug, and so Lilly made a contribution to this joint
20 venture. It was -- it was not a licensing deal. It
21 was a formation of a joint venture where Icos was going
22 to have continuing responsibilities that Lilly was
23 partially funding. So, it's a very different
24 situation.

25 Q. Okay. Just to cut this short, obviously I have

1 some more post-'97 deals to go through here, but to cut
2 it short, let me ask you about a deal in 1992.

3 A. Okay.

4 Q. And that's between Lilly and Centocor.

5 A. Okay.

6 Q. Did you look at that deal when you were
7 comparing the up-front payment that Schering made?

8 A. I don't recall, but if you'll -- I mean, if I
9 could look at the subject matter of it. I don't recall
10 specifically 1992 Centocor/Lilly. Those aren't
11 triangulating on me.

12 Q. Let's go to SPX 1331.

13 A. 1331. Okay.

14 Q. This is from a publication called
15 Pharmaceutical Strategic Alliances, 4th Edition,
16 January 1992 to June 1993. Do you see that?

17 A. Yes.

18 Q. It says it's a directory and analysis of 612
19 pharmaceutical strategic alliances. Do you see that?

20 A. Um-hum, yes.

21 Q. It's published by Windhover?

22 A. Yes.

23 Q. And again, this is one of the databases that
24 exist out there that capture pharmaceutical alliances,
25 correct?

1 A. Yes.

2 Q. If you'd turn to the next page.

3 A. Page 90?

4 Q. Page 90, correct. It says there, "July 1992,"
5 do you see that?

6 A. Yes.

7 Q. Okay.

8 A. I'm just looking at the original here. Okay.

9 Q. And it says, "Lilly purchased 5% of Centocor
10 for \$50 million (\$25 per share - a 72% premium to
11 market price) and will provide \$50 million related to
12 centoxin development expenses."

13 Do you see that?

14 A. Yes, I do.

15 Q. Did you compare the Schering deal to this deal
16 for centoxin in forming your opinion?

17 A. I don't recall. As I said before, Ms. Shores,
18 I don't recall each individual deal that I -- that I
19 consulted. I know about this deal, and so I -- it was
20 certainly in my, you know, my sensorium, if you will,
21 whether I specifically consulted it now, but I was
22 familiar with it. I know the septic shock area a
23 little bit.

24 Q. Okay. Well, sir, this is bigger than a \$60
25 million up-front payment, isn't it?

1 A. I'm sounding like a broken record, but I have
2 to answer in the context of the way I've answered
3 before. The answer is no.

4 Q. Why not?

5 A. Because first of all, a good chunk of this
6 money was for Centocor stock, and I can tell you that I
7 wish I had bought 5 percent of Centocor back in 1992
8 for \$60 million, and secondly, the other part is for
9 research. So, again, that's not the same thing as
10 writing a check and walking away from it.

11 Q. Okay. Didn't you testify though, sir, that you
12 compared -- you included equity purchases when they
13 were at a premium --

14 A. Yes, that's correct.

15 Q. -- in comparing that to cash?

16 A. That's correct.

17 Q. This one's at a premium, right?

18 A. That's correct, but only the premium portion
19 would I -- you know, would I have counted here.

20 Q. And can you give us a rough estimate of what
21 the premium portion was here?

22 A. Well, if it indeed was 72 percent to market
23 price, and I have to rely on the veracity of this
24 document which, you know, I have no reason to deny,
25 that would be 72 percent of \$50 million. So, you know,

1 roughly \$35 million or so.

2 Q. Okay. And I think the second part of your
3 answer is you don't consider this other \$50 million,
4 right, because that was for research, development
5 expenses?

6 A. Yes, that's totally contingent. That's -- you
7 know, paying -- I believe I testified before, and I
8 hope I'm being consistent in that, is that, you know,
9 when a company pays a licensor to do research, it's
10 paying it -- somebody's got to do the research, and
11 it's either going to be done inside on their nickel or
12 outside on somebody else's nickel or still on their
13 nickel, I should say, and so here they were paying
14 Centocor to do some research that they might have to do
15 otherwise. I mean, that's -- that's not at all the
16 same as a noncontingent cash payment.

17 Q. So, a payment for research isn't the same
18 because you're not -- you're not simply writing a check
19 and walking away from it. Is that what you're saying?

20 A. No, it's not the same. As I testified this
21 morning, Ms. Shores, the key thing is control.

22 Q. It's a yes or no question, Your Honor -- I'm
23 sorry, Dr. Levy.

24 A. I don't even know what the question is anymore.

25 Q. All right, let me ask it again.

1 I think you just testified that you don't
2 consider this other \$50 million relevant because that's
3 not something that the company had to write a check for
4 and just walk away from it. It was for research down
5 the road, over which, I guess given your direct
6 testimony, over which Lilly had some control, right?

7 A. Yes.

8 Q. Okay. If you could go to SPX 1333.

9 A. Okay.

10 Q. This is an SEC filing, Form 10-K?

11 A. Yes.

12 Q. Filed on behalf of Centocor?

13 A. Yes.

14 Q. I'd like you to turn to page 15.

15 A. In the 10-K?

16 Q. Yes, sir.

17 A. Okay. Okay.

18 Q. There's a lot to get on the screen here.

19 It says there at December 31, 1992, the company
20 had cash, cash equivalents and investments of \$163 and
21 some odd million, right?

22 A. Yes.

23 Q. And then it goes on to say, "Cash flows from
24 operations for the year ended December 31, 1992
25 included \$50 million received from Lilly primarily for

1 reimbursement of expenses associated with HA-1A."

2 A. I can only read part of that. Let me look at
3 my own --

4 Q. I'm sorry.

5 A. Yes, okay.

6 Q. Do you see that?

7 A. Yes.

8 Q. Centocor got that money in 1992, did it not?

9 A. I mean, I presume their -- I mean, that's in
10 their 10-K. I presume it's correct.

11 Q. And in fact, sir, that's something that Lilly
12 had to pay Centocor at the time it did the deal. Is
13 that not correct?

14 A. I -- I can't testify to that.

15 Q. Well, if it were, if that were money that Lilly
16 had to pay Centocor at the time it did the deal, you'd
17 be wrong in your opinion that the \$60 million was the
18 largest up-front payment ever in the history of the
19 industry, wouldn't you?

20 A. No.

21 Q. Well, there's nothing contingent -- if I'm
22 right, it was something that Lilly had to pay at the
23 time it did the deal, then there would be nothing
24 contingent about that payment, right?

25 A. This isn't a license fee. They're paying for,

1 you know, for -- for research.

2 Q. So, it's your expert testimony that this --
3 that this deal was not a license agreement?

4 A. That is not -- that's not what I said. I
5 said -- you know, you're -- you're -- you're trying to
6 get me to mischaracterize reality, and I'm having
7 difficulty, you know, letting you do that.

8 Q. All right. Now, I spared you the exercise of
9 going through a whole bunch of other deals after 1997
10 in which very large up-front payments, I think even you
11 would agree with me, that they were up-front,
12 noncontingent payments were made. You are aware of
13 those, aren't you?

14 A. Yes. Ironically, Ms. Shores, not many even
15 after '97, if you are going to bring up the recent
16 ImClone/BMS deal, but even you have not been able to
17 find too many of them after '97. You guys have been
18 trying.

19 Q. Excuse me?

20 A. You're trying very hard, but you -- but there
21 really -- you know, I mean, it is still an exception.

22 Q. Okay. Could you turn to SPX 1335.

23 A. Okay.

24 Q. This is a PriceWaterhouse Coopers publication
25 entitled Pharmaceutical Sector Insights. Do you see

1 that?

2 A. I see it.

3 Q. And if you could go to page 49.

4 A. Okay.

5 Q. Let me -- do you see it -- there's a page
6 entitled The Licensing Way? Do you see that?

7 A. Yes, I see it.

8 Q. And then this is extremely hard to read, almost
9 impossible on the ELMO --

10 MR. SILBER: Your Honor, if I could object, we
11 don't know what this document is. This does not appear
12 to be a complete copy of this document. It appears to
13 start for a couple pages and then pick up at 49, and it
14 also seems to refer to merger and acquisition
15 transactions.

16 MS. SHORES: I think we will get to what it's
17 about, Your Honor, but again I am using this only for
18 impeachment purposes. I am not trying to get it in
19 evidence.

20 JUDGE CHAPPELL: Can you give Mr. Silber more
21 information about what this is? We could pause.

22 MS. SHORES: Sure, let's pause for a second.

23 (Counsel conferring.)

24 MR. SILBER: Your Honor, Mr. Raofield has
25 represented to me that when you download this off the

1 web, it doesn't give you the complete version, so we
2 don't know what the complete version of this is. And
3 secondly, we don't know and there has been no
4 foundation established as to why this is authoritative
5 and can be used in any way to impeach Dr. Levy's
6 testimony.

7 MS. SHORES: Your Honor, could Mr. Raofield
8 respond to that?

9 JUDGE CHAPPELL: Sure.

10 MR. RAOFIELD: Your Honor --

11 JUDGE CHAPPELL: He's there, he's so eager, I
12 am going to let him.

13 MR. RAOFIELD: I'm the one who actually
14 downloaded this, and it's --

15 JUDGE CHAPPELL: We're not pointing the finger
16 of blame right now.

17 MR. RAOFIELD: -- and it's a Price Waterhouse
18 document on the pharmaceutical industry, and as I just
19 explained to Mr. Silber, the contents page shows that
20 there are various sections of this large document. The
21 one section that -- the part of the pharmaceutical
22 industry document that is entitled Licensing is the
23 document that he has been given, the entire section on
24 licensing. That is how it happens when you download --
25 that is exactly what it prints out, the entire section

1 on licensing.

2 In fact, this table of contents that I showed
3 to Mr. Silber explains exactly that, and you can see
4 that this is the section on licensing.

5 MR. SILBER: Your Honor, I don't see how this
6 is an authoritative document to use with Dr. Levy for
7 impeachment. Earlier in this trial, we attempted
8 impeachment using a Business Week article, and the
9 ruling on that was that that was not an authoritative
10 document and could not be used for impeachment.

11 JUDGE CHAPPELL: Was the ruling it couldn't be
12 used for impeachment or it couldn't be read into the
13 record?

14 MR. SILBER: Well, I am going to have to refer
15 back to Mr. Orlans for this, if we could have another
16 guest appearance.

17 MR. ORLANS: Your Honor, I was reading it, but
18 that's the way you would impeach a witness, is to
19 produce the document, read it to him, get him to agree
20 it's authoritative and then read it. We had this --
21 essentially the same issue with respect to that
22 document. The bottom line is, has the witness
23 recognized it as an authoritative source or not, and I
24 don't think that has happened here, nor did it happen
25 in the case of the Business Week document.

1 MS. SHORES: Your Honor, could I respond?

2 JUDGE CHAPPELL: I think most of us understand,
3 Mr. Orlans, how to impeach a witness, thank you.

4 Ms. Shores, I'm not sure where you're going
5 here. Maybe we can clear up some of this. If you want
6 to ask him if he's aware of something, that's fine, but
7 I do agree with complaint counsel, I'm not going to let
8 this be an exhibit or pushed into evidence under the
9 auspices of impeachment.

10 MS. SHORES: Your Honor, I absolutely am not
11 trying to push it into evidence under the auspices of
12 impeachment, I am not trying to do that. He has said
13 that he's relied on publications to form his opinion
14 that the \$60 million was the biggest deal in the
15 industry. I think I'm entitled to refer to other
16 publications to rebut that, to impeach him.

17 JUDGE CHAPPELL: Well, we have an objection
18 here that this is not reliable or authoritative, so I
19 am going to allow you to lay the proper foundation, and
20 I am sustaining the objection subject to you
21 demonstrating some reliability here.

22 BY MS. SHORES:

23 Q. Dr. Levy, have you heard of PriceWaterhouse
24 Coopers?

25 A. Yes.

1 Q. What is PriceWaterhouse Coopers, sir?

2 A. Largely an accounting firm.

3 Q. Do they from time to time do reports on various
4 sectors in the industry?

5 A. Yes.

6 Q. In fact, do they do from time to time reports
7 on the pharmaceutical sector?

8 A. I -- I presume so, but I don't know that.

9 Q. You've never seen a PriceWaterhouse Coopers
10 document on the pharmaceutical sector?

11 A. I believe I have, but I just don't want to
12 testify to their expertise.

13 Q. Well, how about other big accounting firms, do
14 they sometimes do reports on the pharmaceutical sector?

15 A. Yes, they do.

16 Q. And you've seen those?

17 A. As I said, I --

18 Q. Not a particular one, but just generally, you
19 have seen big accounting firms' reports on the
20 pharmaceutical sector?

21 A. Yes, I have.

22 Q. All right --

23 MR. SILBER: Your Honor, I still object to the
24 use of this document. Dr. Levy has testified already
25 as to what resources he used and what he thinks is

1 authoritative. This is not among them.

2 MS. SHORES: Your Honor, he mentioned a whole
3 bunch of different publications. Again, I think it's
4 fair impeachment for me to rely on a document that he's
5 just testified is something that he's generally
6 familiar with, documents that are prepared by big
7 accounting firms.

8 JUDGE CHAPPELL: What's the point you're trying
9 to make?

10 MS. SHORES: The point I'm trying to make, Your
11 Honor, is he just testified that I would not be able to
12 find many deals done after 1997 in which big up-front
13 payments were made.

14 JUDGE CHAPPELL: Well, I'll allow you to ask
15 him a question, and you may refer to that document, but
16 I don't want you to use the document, and you can
17 demonstrate your point that he's unaware of whatever it
18 is you're trying to bring out here.

19 MS. SHORES: Okay, well, just to be clear then,
20 you don't want me to put it on the ELMO and -- fine,
21 I'll just read.

22 BY MS. SHORES:

23 Q. If you could turn to page 50, sir.

24 MR. SILBER: Your Honor, if I may, I'm a little
25 confused. I expected that your ruling was that she

1 would not be using this document with Dr. Levy and have
2 him read from the document, whether it's --

3 MS. SHORES: Fine, okay, I'll --

4 JUDGE CHAPPELL: That's fine. Just so we're
5 clear, you can cross examine this witness and test the
6 basis and the veracity and the strength of his
7 opinions, ask him, for example, are you aware that XYZ
8 paid, you know, this drug company \$18 billion?

9 MS. SHORES: I've got it, got you.

10 JUDGE CHAPPELL: You can make your point that
11 way.

12 MS. SHORES: Okay, thank you, Your Honor. I'm
13 slow, but I'm getting it.

14 BY MS. SHORES:

15 Q. Dr. Levy, isn't it true that the number of
16 hundred million dollar plus deals has grown
17 significantly in the 1996-1997-1998 time frame?

18 A. The reason I'm hesitating again, you included
19 1996 in there. There's been an escalation of these
20 deals in the -- oh, I would say the 1999-2000, perhaps
21 a little bit into 1999, you know, I wouldn't take it
22 back to 1996, because then I would be disagreeing with
23 myself, okay, and I still stand by what I said before.

24 Q. Okay.

25 A. And in terms of the comment that there have

1 been some deals, you know, since 1998 or so that are
2 larger, I have not disputed that. So, that's an
3 increase. If anything -- I mean, there were zero
4 before '97, and so now that there are some, that's an
5 increase.

6 Q. But there was an escalation, at least you'll
7 admit, after 1997, there was an escalation of deals in
8 which big up-front payments were made. Is that right?

9 A. Well, 1999, 2000, 2001 is after 1997, so yes.

10 Q. If you could turn to -- let me just ask you the
11 question before I get into an objection.

12 Let me ask you if you agree with this -- well,
13 I'm going to show it to you. We will see if I can get
14 away with this or not. Can you look at SPX 1334?

15 A. Am I in the same -- this is a different
16 article?

17 Q. Different article.

18 A. Okay. Okay, I'm there.

19 Q. This is a Signals -- another Signals Magazine
20 article?

21 A. I don't know what it is. Yes, okay.

22 Q. Do you see that?

23 A. Yes.

24 Q. It says here, "It wasn't so long ago that any
25 deal valued at more than \$100 million

1 (pre-commercialization) was something to shout about.
2 Eye-popping price tags - such as the \$125 million that
3 SmithKline Beecham Corp agreed to pay for access to
4 Human Genome Sciences Inc.'s human gene sequence data
5 and technology in May 1993 - were as rare as hen's
6 teeth and continued to be so through 1996 or so. By
7 1997, however, the rules had started to change."

8 Do you agree with that?

9 A. I agree with -- I agree with some parts of
10 that. You know, you're asking me do I agree with that
11 statement? I don't think I would have written that
12 statement that way.

13 Q. Well, do you agree that by 1997, there started
14 to be a lot more deals with big up-front payments?

15 A. No, I don't agree with that.

16 Q. It says -- it goes on to say, I'll ask you if
17 you agree with this, "A significant number of new
18 alliances were easily breaking the \$100 million barrier
19 - until Millennium Pharmaceuticals, Inc. left them all
20 behind in the dust when it signed a \$343 million Plant
21 Genomics Alliance with Monsanto Co."

22 Are you familiar with that deal?

23 A. Yes, I am, and you're asking me to answer your
24 questions and you are grossly mixing metaphors here.
25 You know, you're jumping very facilely from up-front

1 payment to total deal value, and if you are going to do
2 that, then I have to go back to my direct testimony and
3 show how that is grossly misleading to the Court.

4 Secondly, you're bringing into play here, which
5 is what the Millennium deal was, research and
6 development alliances. That is not a license deal.
7 You know, Millennium is the number one company in the
8 world in genomics research, and this was a research and
9 development alliance to produce -- I suspect the
10 licensee hoped to get dozens or hundreds of drugs out
11 of this. They weren't licensing one drug.

12 And so, you know, if you want to try to, you
13 know, talk about these numbers, then I think you have
14 to be fair and accurate about it and not compare apples
15 and oranges and zebras and giraffes.

16 Q. I certainly don't want to do that, if you can
17 turn to SPX 1337.

18 A. I'm sorry, where am I now?

19 Q. 1337.

20 A. Okay.

21 Q. This is from the Windhover Database, do you see
22 that at the bottom?

23 A. Yes.

24 Q. It says here, "Top Alliances by Total Deal
25 Value by Quarter."

1 Can you read what it says underneath that, sir?

2 A. I'm sorry, where are you asking me to read?

3 Q. I'm asking you to read what it states
4 underneath that heading.

5 A. Oh, I see. "Total deal value is defined as the
6 sum of all precommercialization payments, including
7 upfront licensing fees, equity purchases, milestones,
8 scheduled R&D payments, and loans."

9 Q. Dr. Levy, Mr. Lauda's not the only person who
10 considers total deal value to be defined as the sum of
11 all precommercialization payments, is he?

12 A. No.

13 Q. If you could -- I'll just keep going briefly
14 with this document, go to the third quarter of 2000.

15 A. Okay.

16 Q. It refers to first a deal between Novartis and
17 SB regarding famvir and vectavir. Do you see that?

18 A. Yes.

19 Q. It says the total deal value there is \$1.6
20 billion. Is that right?

21 A. Yes.

22 Q. There is another one right underneath it
23 between Roche and SmithKline, again, total deal value,
24 \$1.6 billion?

25 A. Yes.

1 Q. Going down to the second quarter of 2000,
2 there's a deal there between Novartis and Vertex, total
3 deal value \$800 million?

4 A. I'm sorry, where are you now?

5 Q. May of --

6 A. Yes, I see that.

7 Q. Do you see that?

8 A deal between Aventis and Millennium, \$450
9 million?

10 A. I see that.

11 Q. April 2000, Guidant and Cordis, \$425 million?

12 A. I see that.

13 Q. And you're aware of that deal?

14 A. I'm actually not aware of that particular deal.
15 I don't know anything about that deal.

16 Q. What about the one underneath that between AHP
17 Wyeth-Ayerst and King, are you familiar with that deal?

18 A. I believe so, but I'm not -- yes, I believe I'm
19 familiar with it.

20 Q. And that's for \$150 million?

21 A. Yes.

22 Q. And how about Cellegene (phonetic) and
23 Novartis, are you familiar with that deal?

24 A. Familiar, yes, but not -- not the details.

25 Q. Let's go the next --

1 A. Again, these are all deal value, I want to
2 emphasize that point. I'm saying yes to you on all
3 these things because you're only asking me whether
4 I'm -- whether I can read. I can read.

5 Q. Well, you're an expert in deals, right?

6 A. Yes.

7 Q. So, you don't have any reason to believe that
8 these numbers are inaccurate regarding total deal
9 value, do you?

10 A. My concern was -- which is -- is that in some
11 way you mischaracterize what these are and what I've
12 said, and that's where I'm, you know, trying to be
13 cautious with you, because you are -- if you're trying
14 to impeach my testimony, I don't in any way feel that
15 this in any way impeaches what I've said, if that's
16 where you're going, and I presume that's what you're
17 trying to do.

18 Q. Well, that's all very interesting, Dr. Levy,
19 but my question is whether you're aware of these deals
20 as a licensing expert.

21 A. Yes, and many of these deals -- in fact, the
22 larger ones were not licenses. They were purchases. I
23 mean, you know, you're reading big numbers, but those
24 big numbers are misleading, and I'm uncomfortable with,
25 you know, your trying to mischaracterize or impeach

1 my -- the veracity of my statements.

2 Q. Let me show you another document.

3 May I approach, Your Honor?

4 JUDGE CHAPPELL: Yes, you may.

5 BY MS. SHORES:

6 Q. This is another document from Windhover. Do
7 you see that on the bottom?

8 A. Yes.

9 Q. And this one is entitled Top Alliances by Total
10 Paid Upfront, by Quarter. Do you see that?

11 A. Right, I see it.

12 Q. And this defines up-front payments as the total
13 of any licensing fees and equity purchases upon deal
14 signing. Is that right?

15 A. I see that, yes.

16 Q. So, in this respect, the way Windhover
17 describes or defines up-front payments, it's a little
18 broader than your definition. Is that right?

19 A. Yes.

20 Q. Now, if you go to the second quarter of 2000?

21 A. Okay.

22 Q. There's a reference to the Aventis/Millennium
23 deal, and in that one, according to Windhover, Aventis
24 paid Millennium \$150 million. Are you aware of that?

25 A. Yes, I am.

1 Q. Is that accurate?

2 A. I believe it is.

3 Q. The next deal, Guidant/Cordis, indicates that
4 there was an up-front payment of \$125 million. Is that
5 accurate?

6 A. Yes. Now, remember this includes equity at
7 market.

8 Q. Um-hum.

9 A. Not equity at premium.

10 Q. Well, we don't really know, unless you can tell
11 us --

12 A. Well, I do.

13 Q. -- whether it was an equity at premium or
14 equity at market.

15 A. With Millennium, I know.

16 Q. How about the next one, is that accurate? It's
17 a co-promotion.

18 A. The co-promotion with King?

19 Q. AHP Wyeth-Ayerst/King, yes.

20 A. Yes, I don't know the details of that.

21 Q. So, you don't know that it was a \$75 million
22 up-front payment?

23 A. As I say, I don't know what component of that
24 \$75 million was equity and what was cash, nor do I know
25 what component of that was equity at premium and cash.

1 Q. And again, just so we can finish with this
2 exhibit, there's a reference in the first quarter of
3 2000 to a CAT Human Genome Sciences deal.

4 A. Yes.

5 Q. In which there was a \$67 million up-front
6 payment? Is that accurate?

7 A. If you include equity in that, that's correct.

8 Q. If you go to the last page of this exhibit --

9 A. The last page?

10 Q. Yes, sir.

11 It's a reference to the fourth quarter of 1998.

12 A. Yes.

13 Q. It references there a deal between P&U and
14 Otsuka America. Do you see that?

15 A. Yes.

16 Q. Are you familiar with that deal?

17 A. I believe so, yes.

18 Q. And in that one, there was, was there not, an
19 \$80 million up-front payment?

20 A. Well, this was a co-marketing deal on an
21 approved drug.

22 Q. I'm asking you whether there was an \$80 million
23 up-front payment.

24 A. It's what it says here. I don't recall that,
25 but...

1 Q. Okay. Now, second of all -- a second ago you
2 were talking about the Aventis/Millennium deal, that's
3 the one you said you knew something about, right?

4 A. Yes.

5 Q. It's on the first page.

6 A. Um-hum.

7 Q. Right? And you said that that was an equity
8 purchase.

9 A. No, I didn't say that. I said that a good deal
10 of that was an equity purchase.

11 Q. Okay. So, part of it was an equity purchase,
12 because you said it wasn't a premium, I think.

13 A. I said I don't recall whether that was a
14 premium. I don't know how much of that was at premium.

15 Q. So, if -- if the transcript, for example, were
16 to say that you had said that it was -- that you were
17 familiar with it and that it wasn't at premium, the
18 transcript would be in error?

19 A. I'm sorry, say that again.

20 Q. If for some reason the transcript said, and I'm
21 referring to your earlier testimony, that this was an
22 equity -- part of this was an equity purchase that was
23 not at premium, the transcript would be in error,
24 right, because you don't know?

25 A. I don't know what you're asking me, Ms. Shores.

1 Q. Let me start again.

2 Let me ask you this: Do you know, sir, whether
3 the portion of this deal, this up-front payment that
4 was an equity purchase, do you know whether or not it
5 was at premium?

6 A. No, I don't.

7 Q. Okay.

8 MS. SHORES: I have nothing further.

9 JUDGE CHAPPELL: Mr. Curran, are you handling
10 the cross?

11 MR. CURRAN: I am, Your Honor.

12 JUDGE CHAPPELL: Ballpark estimate of time?

13 MR. CURRAN: Forty minutes.

14 JUDGE CHAPPELL: Let's go ahead and take our
15 afternoon break. We will recess until 3:25.

16 (A brief recess was taken.)

17 JUDGE CHAPPELL: Mr. Curran, you may proceed.

18 MR. CURRAN: Thank you, Your Honor.

19 CROSS EXAMINATION

20 BY MR. CURRAN:

21 Q. Good afternoon, Dr. Levy.

22 A. Hi, Mr. Curran.

23 Q. Dr. Levy, you derive a material portion of your
24 income testifying as an expert witness, correct?

25 A. No.

1 MR. CURRAN: Your Honor, may I approach the
2 witness?

3 JUDGE CHAPPELL: Yes, you may.

4 MR. CURRAN: Your Honor, I'm having a sticker
5 applied to this document as we speak, and I'll state
6 for the record what that USX number is in just a
7 moment.

8 BY MR. CURRAN:

9 Q. Dr. Levy, do you recognize this document that's
10 been handed to you?

11 A. Yes.

12 Q. Sir, it's a pleading from a court case in which
13 you're involved, correct?

14 A. Yes, it is.

15 Q. And sir, it's a pleading filed by or on behalf
16 of you, correct?

17 A. I think so, yes.

18 Q. This is something filed by your lawyer in state
19 court in Illinois, correct?

20 A. I think so, yes.

21 MR. CURRAN: Your Honor --

22 MR. SILBER: Your Honor, I object to the use of
23 this document. He asked a question about Dr. Levy's
24 income, and now he's going into a pleading about a
25 defamation suit. I don't see the relevance of this

1 document.

2 MR. CURRAN: Your Honor, the relevance of the
3 document will become clear to everyone in the room with
4 my next question.

5 JUDGE CHAPPELL: Well, why do we need the
6 document? Why don't you question him first --

7 MR. CURRAN: I did, Your Honor, and he made a
8 statement inconsistent with a statement that has been
9 made on his behalf in this document.

10 JUDGE CHAPPELL: Okay, that's where you're
11 going?

12 MR. CURRAN: Yes, pure impeachment.

13 JUDGE CHAPPELL: Okay, ask your next question.

14 BY MR. CURRAN:

15 Q. Sir, please refer to paragraph 17 on page 26 of
16 34.

17 A. On page 26?

18 Q. Yes.

19 A. I'm sorry, and what paragraph is that?

20 Q. Paragraph 17. I've put it on the ELMO for your
21 convenience as well.

22 A. Okay.

23 Q. Let me read the paragraph. And again, this is
24 from a pleading filed on your behalf.

25 A. Um-hum.

1 Q. "Levy's good reputation for veracity and
2 honesty are extraordinarily important to him, because
3 he derives a material portion of his income testifying
4 as a leading expert witness for the Federal Trade
5 Commission regarding matters administered by the FTC's
6 Bureau of Competition and the United States Internal
7 Revenue Service regarding the Research and
8 Experimentation Tax Credit."

9 Did I read that correctly, sir?

10 A. Yes, you did.

11 Q. And this is a court filing made on behalf of
12 you, correct?

13 A. Yes.

14 Q. So, sir, let me ask you again, do you derive a
15 material portion of your income testifying as an expert
16 witness?

17 A. When I answered your question before -- I'm
18 sorry, I mean, the operative word there is "material,"
19 and it is a -- you know, as I think I testified earlier
20 in my direct or my cross examination, it's, you know, 5
21 or 10 percent, and I -- when I said no to your question
22 before, I still don't think that, you know, 5 or 10
23 percent in the context of when I answered you -- you
24 know, I said no.

25 Now, is 5 or 10 percent material? The number

1 is 5 or 10 percent. In this last year -- and it's
2 much -- as I've also testified earlier, this was sort
3 of an unusual year for me. Usually I don't do any.
4 So, you know, you asked me a very general question, and
5 I think I answered you honestly.

6 Q. Okay, well, I'll ask the question in the
7 present tense. Do you derive a material portion of
8 your income testifying as an expert witness?

9 JUDGE CHAPPELL: To save us some more time,
10 make sure he and you understand what "material" means.

11 MR. CURRAN: Well, Your Honor, I'm using the
12 word "material," and Dr. Levy, I'm using the word
13 "material" in the same sense that your attorney used it
14 in that paragraph, okay?

15 MR. SILBER: Objection as to how he knows what
16 the attorney meant in that paragraph.

17 THE WITNESS: Sir, I --

18 JUDGE CHAPPELL: Hang on a second.

19 THE WITNESS: Oh, I'm sorry.

20 JUDGE CHAPPELL: I suppose you're objecting on
21 foundation grounds, and I'll sustain that. If you are
22 going to use that definition, you need to -- let's just
23 have an understanding that you and he are on the same
24 wavelength on the term "material."

25 MR. CURRAN: Sure.

1 BY MR. CURRAN:

2 Q. Dr. Levy, who's your attorney in that court
3 case?

4 A. Keevan Morgan.

5 Q. What's his name?

6 A. Keevan, K E E V A N, M O R G A N.

7 Q. Is that an individual or a firm?

8 A. No, his firm is Morgan & Blye (phonetic).

9 Q. Did you and Mr. Morgan review that document
10 together before you signed it -- before he submitted
11 it?

12 A. Yes, we did. Yes.

13 Q. Let me restate the question, because we were
14 speaking over one another.

15 Did you review that pleading before your
16 lawyer, Mr. Morgan, filed it?

17 A. Actually not when he filed it. I was out of
18 town for a couple weeks. I was actually here a good
19 deal of the time, so I didn't review this specifically,
20 but I do recall his asking me about that, and at the
21 time, he asked me what percentage of my income, you
22 know, I'm deriving from being an expert witness this
23 year, because I have to file my tax returns, you know,
24 as part of the discovery in this matter, and I told him
25 that it would be somewhere between 5 and 10 percent.

1 He then chose the word "material," okay? I
2 didn't choose that word. I really don't know what
3 "material" means.

4 Q. Now, sitting here right now, is this the first
5 time you've ever seen that document?

6 A. No, sir.

7 Q. Have you instructed Mr. Morgan to correct that
8 paragraph in the pleading?

9 A. No, I haven't.

10 Q. Now, sir, in your direct testimony this
11 morning, you said that all sustained release forms of
12 niacin up to the time of Schering's due diligence had
13 been quite significantly toxic and had not been on the
14 market, correct? Do you remember saying that?

15 A. I don't recall saying exactly those words, but
16 I remember saying something like that.

17 Q. Sir, have you ever heard of Slo-Niacin?

18 A. Yes, I have.

19 Q. What's Slo-Niacin?

20 A. I believe that's the form of sustained release
21 niacin that Upsher-Smith sells.

22 Q. Does that look like Slo-Niacin to you?

23 A. I have not seen the product.

24 MR. CURRAN: May I approach, Your Honor?

25 JUDGE CHAPPELL: Yes, you may.

1 BY MR. CURRAN:

2 Q. Does that look like Slo-Niacin?

3 A. As I said, I mean, it looks like -- the box
4 says "Slo-Niacin." I don't know -- since I don't know
5 what it looks like, I have no --

6 Q. What's your understanding as to when Slo-Niacin
7 went on the market?

8 A. I don't know.

9 Q. Would it surprise you to know that Slo-Niacin's
10 been on the market since the late 1980s?

11 A. I said I don't know.

12 Q. Would that surprise you? Would it surprise you
13 to know that?

14 A. Would it surprise me to know that? No.

15 Q. Would it surprise you to know that Slo-Niacin
16 is an extended release niacin?

17 A. Not at all.

18 Q. So, sir, you were wrong when you said on direct
19 that there had -- that there were no sustained release
20 forms of niacin on the market back in 1997, correct?

21 A. Well, first of all, I don't -- I don't recall
22 saying that. What -- you know, I mean, what I'm
23 meaning to say in all of this -- and I think, you know,
24 this is where, you know, we're maybe just not
25 understanding each other or the questions.

1 To my knowledge, the FDA has not approved any
2 sustained release forms of niacin prior to Niaspan, and
3 whenever I answer a question like this, I'm not
4 considering, you know, vitamins and health food store
5 types of products, over-the-counter products, and I
6 believe that this is one such product.

7 Q. Now, sir, if you said on direct, "all sustained
8 release forms of niacin" were "not on the market" in
9 1997, that would have been an overstatement, correct?

10 A. If I said -- if I said it exactly that way,
11 that would have excluded these OTC products and these
12 health food store type products, and I would have been
13 incorrect.

14 Q. Okay.

15 Your Honor, I have another document for the
16 witness. May I approach?

17 JUDGE CHAPPELL: Yes.

18 BY MR. CURRAN:

19 Q. This is USX 1648. Sir, this is an article that
20 appeared in the Mayo Clinic's publication in September
21 1992 regarding time-release nicotinic acid in the
22 treatment of patients with low HDL-C. Do you see that?

23 A. Yes, I do.

24 Q. And it's written by Dr. Ray Squires and others,
25 correct?

1 A. Yes.

2 Q. Sir, at the bottom of the summary on the first
3 page, do you see where it says, "We conclude that
4 therapy with low-dose, time-release nicotinic acid
5 results in clinically significant improvement in HDL-C
6 levels and in the entire blood lipid profile in
7 selected patients with depressed HDL-C concentrations"?

8 A. Yes, I see that.

9 Q. Do you see that? And sir, if you turn to page
10 859, and that is the second to last page of this
11 document, do you see where it says -- and I've put this
12 on the ELMO for your convenience -- do you see where it
13 says, "The extensive clinical experience with
14 time-release nicotinic acid, periodic monitoring of
15 liver enzymes has revealed that serious hepatotoxicity
16 is uncommon, and we continue to recommend its use for
17 the treatment of hyperlipidemia in selected patients"?

18 A. I see that.

19 Q. Sir, next look, please, at page 856 within this
20 document.

21 A. 856.

22 Q. And in particular there, sir, on the second
23 column --

24 A. Excuse me, I'm just not there yet.

25 Q. Sure, the second column, first full paragraph,

1 page 856. Do you see that the product used in this
2 study was Slo-Niacin? Do you see that, sir?

3 A. I see that here, yes, sir.

4 Q. Thank you.

5 Your Honor, I have an additional article I'd
6 like to show to the witness.

7 JUDGE CHAPPELL: You may. I don't need a copy
8 if you're going to put that on the ELMO.

9 MR. CURRAN: Very good. Thank you, Your Honor.
10 Your Honor, this one is designated USX 1649.

11 BY MR. CURRAN:

12 Q. Sir, this is an article by Dr. Carl Lavie and
13 others that appeared in the American Journal of
14 Cardiology on April 15th, 1992. Do you see that?

15 JUDGE CHAPPELL: Mr. Curran, why don't you give
16 him a minute to review it.

17 MR. CURRAN: Of course, Your Honor.

18 THE WITNESS: Yes, I see that.

19 BY MR. CURRAN:

20 Q. And Dr. Levy, the title of this article is,
21 "Marked Benefit With Sustained-Release Niacin Therapy
22 in Patients With "Isolated" Very Low Levels of
23 High-Density Lipoprotein Cholesterol and Coronary
24 Artery Disease," correct?

25 A. Yes.

1 Q. And sir, the sustained release niacin used in
2 this study was Upsher-Smith's Slo-Niacin. Do you see
3 that on the first full page of the article?

4 A. I don't -- I mean, I --

5 Q. Let me refer you specifically to that section.
6 Do you see in the first column where the italics begin,
7 second full paragraph?

8 A. Yes, I see it.

9 Q. And again, sir, there's reference to the
10 Slo-Niacin being the product used there, correct?

11 A. Yes.

12 Q. Sir, now, I'd like to direct your attention to
13 that same page, 1083, and sir, now over to the second
14 column. Do you see where the authors write:

15 "There were no significant changes in --"

16 A. I don't see it -- I see something different
17 highlighted here, sir.

18 Q. Actually, it starts on the bottom of 1083 and
19 continues to the top of page 1084, if that's helpful,
20 and it says --

21 A. So, you are not talking about the highlighted
22 section that you had there?

23 Q. That's right, I guess we will come back to that
24 one. That one talks about marked improvement in total
25 cholesterol, correct, but then the sentence after --

1 the sentence at the end of 1083 begins, "There," and it
2 continues to the next page, "were no significant
3 changes --"

4 A. I see that.

5 Q. " -- in aspartate transaminase during the time
6 period of the study," correct?

7 A. That's what it says.

8 Q. And this is, again, a 1992 study, correct?

9 A. Correct.

10 Q. Now, sir, are you aware that Ms. Lori Freese
11 testified in this court proceeding?

12 A. I don't recall -- I know I've not seen her
13 testimony, but I don't -- I just don't know, sir.

14 Q. Do you know who she is?

15 A. No, I don't.

16 Q. Sir, then you're not aware that she testified
17 that Slo-Niacin and Niacor-SR are virtually the same
18 product?

19 A. I am not familiar with -- I -- as I say, I
20 don't know her -- I don't know who she was -- I don't
21 know who she is and I don't believe I've seen her
22 deposition.

23 Q. Sir, you don't dispute that she testified that
24 Slo-Niacin and Niacor-SR are virtually the same
25 product, do you?

1 A. I have no basis -- I don't know who the woman
2 is, so I can't say anything about what she said or
3 didn't say, sir.

4 MR. CURRAN: Your Honor, I have another
5 document to show the witness.

6 JUDGE CHAPPELL: Go ahead.

7 MR. CURRAN: I'll be putting this one on the
8 ELMO again, Your Honor.

9 JUDGE CHAPPELL: Thank you.

10 BY MR. CURRAN:

11 Q. This one is marked USX 1041.

12 By the way, Dr. Levy, the term I stated before
13 and tried to pronounce correctly, aspartate
14 transaminase?

15 A. Right.

16 Q. That's -- that refers to liver function tests,
17 correct?

18 A. It's one of the two liver enzymes that we've
19 talked about a lot in this trial.

20 Q. Sir, do you have USX 1041 in front of you?

21 A. Yes, sir.

22 Q. Have you seen this document before?

23 A. I don't think I've seen this document.

24 Q. Let me refer your attention to the first page
25 under the section titled Brief Profile of Niacor-SR?

1 A. Okay.

2 Q. Do you see that, sir?

3 A. Yes.

4 Q. Do you see the sentence where it states, "The
5 nutritional supplement Slo-Niacin (currently being
6 marketed) is nearly identical to Niacor-SR"?

7 A. Yes, I see that.

8 Q. And again, sir, this is a document -- these are
9 meeting notes from May 12th, 1995, correct?

10 A. That's -- yeah, I think that's what it says.

11 Q. You don't dispute that, do you?

12 A. No, of course not.

13 Q. But like Ms. Freese's testimony, that's a
14 document that you did not take into account in forming
15 your opinions in this matter?

16 A. I don't recall this document, as I said.

17 Q. Sir, when you were last here, you testified
18 that you didn't do a net present valuation analysis on
19 Niacor-SR, correct?

20 MR. SILBER: Objection, Your Honor, this is
21 outside the scope of direct. He did not speak to net
22 present value at all in his direct testimony.

23 MR. CURRAN: That's wrong, Your Honor. Dr.
24 Levy not only spoke about Niacor-SR not being worth \$60
25 million, one of the charts he put on the overhead or

1 that was put on the screens by computer stated
2 something about \$60 million being -- or is still
3 grossly excessive for Niacor-SR, and I just want to
4 establish that Dr. Levy's got no further basis at this
5 time than he did back when he testified two months ago
6 for that conclusion.

7 MR. SILBER: Your Honor, Dr. Levy stated the
8 basis for his opinion by looking at the payments.
9 His -- he did not have any testimony on net present
10 value.

11 MR. CURRAN: Well, of course, he's avoiding
12 that subject.

13 JUDGE CHAPPELL: If he testified about the
14 payment, Mr. Curran has the right to test the
15 foundation of that opinion. I'll allow it. Overruled.

16 MR. CURRAN: Thank you, Your Honor.

17 BY MR. CURRAN:

18 Q. Okay, sir, when you were last here, you
19 testified that you didn't do a net present value
20 analysis on Niacor-SR, correct?

21 A. Correct.

22 Q. And you still haven't done one, correct?

23 A. Correct.

24 Q. And you also testified you didn't do a net
25 present value analysis on Klor Con 8, correct?

1 A. Klor Con 8? Yes.

2 Q. And you still haven't done one, correct?

3 A. Correct.

4 MR. SILBER: Your Honor, I have -- he's going
5 through what Dr. Levy testified to in his direct in our
6 case in chief. He was cross examined on these issues
7 when they did cross examine on his testimony in the
8 case in chief. He's just repeating what he did back
9 after Dr. Levy provided his original testimony.

10 JUDGE CHAPPELL: Well, I agree, we don't need
11 to get into details on Klor Con 8, 10, 20, 55,
12 whatever. You've made your point about net present
13 value, so move along.

14 BY MR. CURRAN:

15 Q. Now, Dr. Levy, are you aware that a witness
16 appeared in this courtroom last Friday and testified as
17 follows --

18 MR. SILBER: Objection, vague, Your Honor.

19 MR. CURRAN: I'm not through with the question,
20 Your Honor. May I complete the question?

21 JUDGE CHAPPELL: Go ahead.

22 BY MR. CURRAN:

23 Q. Dr. Levy, are you aware that a witness
24 sponsored by complaint counsel appeared in this
25 courtroom last Friday and testified as follows:

1 "QUESTION: Mr. Egan, Searle did net present
2 value calculations when evaluating in-licensing
3 opportunities, did it not?

4 "ANSWER: Yes.

5 "QUESTION: And those net present value
6 calculations were based on anticipated cash flows,
7 right?

8 "ANSWER: That's right, discounted cash flows.

9 "QUESTION: It's pretty typical of
10 pharmaceutical companies to do net present value
11 calculations when evaluating licensing deals, is it
12 not?

13 "ANSWER: Yes."

14 Again, my question is, are you aware that a
15 witness sponsored by complaint counsel testified to
16 that effect in this courtroom in that chair last
17 Friday?

18 A. I am aware only that Mr. Egan testified. I
19 don't know when, where or anything of the sort. Again,
20 many months ago, I believe -- I believe I read either a
21 report or a deposition -- I think it was a deposition
22 of Mr. Egan's testimony, and that's --

23 Q. Now, sir, you're aware that Mr. Egan formerly
24 worked at Abbott, correct?

25 A. No, I'm not aware of that at all.

1 Q. Sir, who is Jean Davignon?

2 A. I don't know.

3 Q. Sir, who is Donald B. Hunninghake?

4 A. I don't know.

5 Q. Sir, who is Stephanie Kafonek?

6 A. I don't know.

7 Q. Sir, who is Robert A. Kreisberg?

8 A. It's familiar, but I just don't recall who it
9 is.

10 Q. Sir, who is Valery T. Miller?

11 A. I don't know.

12 Q. Sir, who is Richard C. Pasternak?

13 A. I don't know.

14 Q. Sir, who is Evan Stein?

15 A. I don't know.

16 Q. Sir, who is B. Greg Brown?

17 A. Oh, I believe I've met Greg Brown somewhere,
18 but I just don't place him now.

19 Q. Do you recall the context in which you may have
20 met this Dr. Brown?

21 A. You know, I really don't want to guess. I --
22 it -- if you forced me to guess, I believe it was at
23 the Licensing Executives Society annual meeting. I
24 think he went to one of my seminars. So, I -- but I --
25 you know, I just don't recall.

1 Q. That's got to be a vague recollection.

2 A. Yes.

3 Q. Sir, have you ever heard of the Niacin Advisory
4 Committee that Upsher-Smith organized?

5 A. No.

6 MR. CURRAN: Your Honor, I have another
7 document I'd like to show the witness.

8 JUDGE CHAPPELL: Go ahead.

9 BY MR. CURRAN:

10 Q. This is USX 329. Sir, the first page of USX
11 329 lists the members of Upsher-Smith's Niacin Advisory
12 Committee, correct?

13 A. Um-hum, yes.

14 Q. And you see there that Dr. Greg Brown is
15 listed?

16 A. Yes, I do.

17 Q. And Dr. Jean Davignon?

18 A. Yes.

19 Q. And Dr. Donald Hunninghake?

20 A. Yes.

21 Q. And Dr. Stephanie Kafonek?

22 A. Yes.

23 Q. And Dr. Robert Kreisberg?

24 A. Yes.

25 Q. And Dr. Valery Miller?

1 A. Yes.

2 Q. And Dr. Richard Pasternak?

3 A. Yes.

4 Q. And Dr. Evan Stein?

5 A. Yes.

6 Q. Now, sir, can you please turn to page 67 of
7 that exhibit, giving you only the last two digits? I'd
8 like to turn your attention to Dr. Brown's biographical
9 information.

10 A. Okay.

11 Q. Sir, did you know that Dr. Brown is a professor
12 of cardiology at the University of Washington?

13 A. As I said, I don't -- I don't know Dr. Brown,
14 so I'm -- you know, I'm -- I didn't know where he was.
15 I think, you know, some of these names were fairly
16 common names, so Greg -- you know, Gregory Brown -- I
17 mean, not Jean Davignon, but -- and I just didn't place
18 him at the time when you asked me the question before.

19 Q. I'm sorry, do you place him now?

20 A. I still don't know him, and so if you're asking
21 me, you know, do I know him, I don't know him.

22 Q. Okay. So, you don't know that he was on the
23 editorial board of the American Journal of Cardiology
24 and Circulation?

25 A. I would not know that. I don't read those

1 journals.

2 Q. Do you see the reference there to FATS?

3 A. Yes, I see that.

4 Q. Do you see the reference there to FATS II?

5 A. Yes.

6 Q. Do you know what that refers to?

7 A. No, I don't.

8 Q. You've never heard of the FATS study?

9 A. I've heard of the FATS study. I don't know if
10 this is what that's referring to or not.

11 Q. Oh, okay. Have you heard of the FATS follow-up
12 study, FATS II?

13 A. I have heard -- I'm not even sure I've heard of
14 that. I mean, I don't know what -- you know, if you're
15 asking me, you know, can I recite it to you chapter and
16 verse, the answer is no.

17 Q. Well, you said a moment ago you recalled
18 something about the FATS study. Is that not what you
19 said?

20 A. Yes, and I don't recall whether it's FATS I,
21 FATS II, I just -- you know, there's a lot of
22 literature.

23 Q. What's your best current recollection of what
24 the FATS study was about?

25 A. I just don't know, sir.

1 Q. What's your best current recollection of what
2 the FATS II study was about?

3 A. I am not going to venture a guess on that
4 either.

5 Q. Sir, did you know that Dr. Brown was the one
6 who conducted those studies?

7 A. No, I didn't.

8 Q. Sir, are you aware that Dr. Brown used
9 Upsher-Smith's Slo-Niacin product for the FATS II
10 study?

11 A. I have no idea.

12 MR. SILBER: Your Honor, I'd object to this
13 line of questioning. Dr. Levy has already said he
14 doesn't know who Dr. Brown is. Dr. Brown testified
15 here. We've already heard testimony on what Dr. Brown
16 did, what he was involved in. We don't need to go
17 through it again with Dr. Levy, who has said he doesn't
18 know who Dr. Brown is.

19 MR. CURRAN: Sir, I'm -- Your Honor, I'm not
20 belaboring anything, and I don't blame Mr. Silber for
21 trying to help out his witness here, but what I'm
22 trying to do is show that this witness isn't familiar
23 with the history of the clinical studies and other
24 academic studies and so forth done on Slo-Niacin, which
25 is essentially identical to Niacor-SR, and in the

1 process of doing this, I'm also trying to contrast the
2 backgrounds and expertise of Dr. Levy as opposed to the
3 members of the Upsher-Smith blue ribbon panel.

4 JUDGE CHAPPELL: Is this document in evidence?

5 MR. CURRAN: This one -- this one is, Your
6 Honor, yes.

7 JUDGE CHAPPELL: Well, you may ask him anything
8 about a document in evidence; however, if I understand
9 the legal bases for the objection, Mr. Silber, you may
10 not bolster the character or credibility of these
11 people who haven't been attacked.

12 MR. CURRAN: Absolutely, Your Honor.

13 JUDGE CHAPPELL: If he doesn't know them, he
14 doesn't know them, so there's no need to dwell on it.
15 You can ask him -- if this is in evidence, you can ask
16 him if he's aware of them, but we don't need to go into
17 any more detail than that.

18 MR. CURRAN: Right, that's my sole intention,
19 Your Honor.

20 BY MR. CURRAN:

21 Q. So, Dr. Levy, are you or are you not aware that
22 Upsher-Smith's Slo-Niacin product was used in the FATS
23 II study?

24 A. I am not aware of that.

25 Q. Have you ever heard of the HATS study, H A T S?

1 A. I -- I just am not -- I'm not recalling it now,
2 sir.

3 Q. So, then, you're not aware that Upsher-Smith's
4 Slo-Niacin product was used in that study as well, are
5 you?

6 A. No.

7 Q. Sir, do you now recall who Dr. Jean Davignon
8 is?

9 A. Recall? As I said, I didn't know him or her
10 before and I don't know him any more having seen this
11 piece of paper. No, I don't.

12 Q. Okay. So, there's no use in me going through
13 Dr. Davignon's background here. That's not going to
14 refresh your recollection?

15 A. No, I don't know the person.

16 Q. Sir, do you see reference there to -- I'm
17 sorry, on the next page, sir, I'd like to ask you to
18 refer to the last two digits page 68.

19 A. Okay.

20 Q. Do you see reference on that page under the
21 name Donald B. Hunninghake to NCEP Expert Panel?

22 A. Yes, I see that.

23 Q. What's the NCEP?

24 A. I don't know what that acronym is.

25 Q. You've never heard of it?

1 A. I've probably heard of it, sir, but I don't see
2 any need to guess since I'm sure you're going to tell
3 me what that acronym stands for. I just don't know.

4 Q. Yeah, but you see, what we're doing here, I'm
5 trying to show that you don't know what you're talking
6 about, okay? So, I'm trying to see if you know what
7 NCEP means. Let me say that again. NCEP, do you know
8 what that means?

9 A. Sir, the answer is no.

10 Q. It's the National Cholesterol Education
11 Program, isn't it?

12 A. If you say so.

13 Q. Sir, this shouldn't take long, but I want to
14 ask you -- do you now recall who Dr. Hunninghake is?

15 A. As I said, I didn't know him before, and I
16 don't know him any better now that --

17 Q. Dr. Kafonek on page 69?

18 A. The same answer, sir.

19 Q. Dr. Kreisberg on page 70?

20 A. Oh, I know where I know him from. Now that I
21 see where he's from, my wife is from Birmingham,
22 Alabama, and I met him down there in some context, but
23 not in a professional context.

24 Q. Do you see the reference there to National
25 Cholesterol Education Program?

1 A. I see that, yes.

2 Q. He's a member of that, a member of the expert
3 panel there, right?

4 A. Yes.

5 Q. Have you ever heard of -- or do you now recall
6 who Dr. Valery Miller is?

7 A. Sir, as I said, I didn't know her before, and I
8 have no reason for this document to have suddenly made
9 me know her.

10 Q. And then the last one on page 71, Dr. Richard
11 C. Pasternak?

12 A. That's a name that I know, but I think I know
13 it from having read the literature. I don't know him.

14 Q. Sir, do you know that Dr. Pasternak was the
15 director of preventative cardiology and cardiac
16 rehabilitation at Massachusetts General Hospital?

17 A. I don't know his resume, sir, you know, I don't
18 make it a habit of -- I have no reason to know, you
19 know, this particular narrow scope of medical
20 practitioners.

21 Q. What do you mean, "narrow scope"?

22 A. You're bringing forth these people who are
23 putative experts on one aspect of cardiology.

24 Q. All right. Sir, referring your attention back
25 to the first page, were you aware that all of these

1 individuals, with the exception of Dr. Miller, who
2 couldn't attend, attended a meeting sponsored by
3 Upsher-Smith in Minneapolis on August 15th and 16th,
4 1996?

5 A. I have no -- as I say, this is the first time
6 I've seen this document, and this is the first time
7 I've known of anything related to this. So, the answer
8 is no.

9 Q. Did you know that the subject of the meeting in
10 Minneapolis was Niacor-SR?

11 A. How would I know that, sir? I don't know about
12 the meeting, so I don't know anything about its
13 subject.

14 Q. Now, sir, we've already established you weren't
15 here for the testimony by Ms. Freese a couple of weeks
16 ago?

17 A. That's correct.

18 Q. So, you're not aware that Ms. Freese testified
19 that Dr. Mark Halvorsen and Dr. Claude Drobnes
20 presented Niacor-SR's efficacy and safety information
21 to the members of this committee?

22 A. Sir, I have no idea what anybody presented on
23 this matter since I know nothing about it. I would say
24 that there -- my context of safety and efficacy
25 information relates to what I've seen in terms of the

1 clinical trials on Niacor-SR, and if you're telling me
2 that they're the same, I've seen those -- I've seen
3 those data. I have not seen data on Slo-Niacin, which
4 is a -- you know, a health food store product that
5 doesn't require safety and efficacy studies.

6 MR. CURRAN: Can I have that question read
7 back, please?

8 (The record was read as follows:)

9 "QUESTION: So, you're not aware that Ms.
10 Freese testified that Dr. Mark Halvorsen and Dr. Claude
11 Drobnes presented Niacor-SR's efficacy and safety
12 information to the members of this committee?"

13 MR. CURRAN: Your Honor, I move to strike the
14 previous answer, at least in part.

15 JUDGE CHAPPELL: I'll disregard after the first
16 sentence, which was responsive.

17 MR. CURRAN: Thank you, Your Honor.

18 BY MR. CURRAN:

19 Q. Dr. Levy, you're not aware, then, that Ms.
20 Freese testified that these -- this panel from the
21 Niacin Advisory Committee had no problem with the
22 safety and efficacy data on Niacor-SR?

23 A. Sir, I know nothing about Ms. Freese, this
24 meeting or anything else that this so-called panel of
25 experts did or didn't do.

1 Q. Sir, we've already established, haven't we,
2 that you're not an expert in cholesterol metabolism,
3 right?

4 A. That's correct.

5 Q. And you're not a cardiologist, correct?

6 A. That's correct.

7 Q. And you're not a lipidologist, correct?

8 A. That's correct.

9 Q. You're not even a state certified toxicologist,
10 are you?

11 A. That's correct.

12 Q. And when you practiced medicine, you didn't
13 specialize in cholesterol diseases, right?

14 A. That's correct.

15 Q. And you don't hold yourself out to be a world
16 class expert in lipid metabolism and drugs that affect
17 it, right?

18 A. Correct.

19 Q. And sir, you've never published any
20 peer-reviewed scientific studies on lipid metabolism or
21 drugs that affect it, correct?

22 A. Correct.

23 Q. And sir, the last time you prescribed a
24 cholesterol-lowering drug was at least 20 years ago,
25 correct?

1 A. Yes, that's correct.

2 Q. And you haven't practiced medicine in 20 years.
3 Isn't that right?

4 A. I've never practiced medicine in the true sense
5 of the word, but I have -- I have -- I'm licensed to
6 practice, and I have seen patients since then, but
7 that's not what I do for a living, but I am licensed to
8 practice medicine, sir.

9 Q. Sir, you haven't practiced medicine in 20
10 years. Isn't that right?

11 A. Sir, I'm licensed to practice medicine, so I
12 can't say -- I don't know how to answer your question.
13 I'm answering it as best I can. I'm licensed to
14 practice medicine in two states.

15 Q. Sir, earlier in this trial, you testified as
16 follows, didn't you:

17 "QUESTION: Sir, how long has it been since you
18 practiced medicine?

19 "ANSWER: Practiced medicine?

20 "QUESTION: Yeah.

21 "ANSWER: Twenty years."

22 Did you give that testimony in open court in
23 this proceeding?

24 A. Yes, I did, and I don't think I've said
25 anything in contradiction to that. I've said simply

1 that I'm licensed to practice. I'm not saying that
2 I've practiced medicine.

3 Q. And sir, you can't say what's generally
4 accepted in the scientific community as to the effects
5 of niacin on blood lipids and coronary vascular
6 disease, correct?

7 A. No, that's not correct. One doesn't have to be
8 an expert or a cardiologist. I dare say that I know a
9 lot more than all those guys on many other aspects of
10 drug discovery, drug development, which is what this
11 case has been a lot about, so one doesn't have to be an
12 expert to be able to read the literature.

13 Q. Let me state this question again.

14 Sir, you can't say what's generally accepted in
15 the scientific community as to the effects of niacin on
16 blood lipids and coronary vascular disease, correct?

17 A. That's not correct, no.

18 Q. Sir, in your deposition, you testified as
19 follows, didn't you:

20 "I don't represent the scientific community
21 that focuses on cholesterol metabolism --" I'm sorry,
22 thank you. Can you read that, sir?

23 A. Yes, I can.

24 Q. Okay.

25 "I don't represent the scientific community

1 that focuses on cholesterol metabolism. I have never
2 proposed or purported myself to be an expert on
3 cholesterol metabolism. And so I don't want to speak
4 for a --" pardon me " -- population of people that may
5 or may not share this opinion."

6 Do you see that?

7 A. Yes.

8 Q. And also, on the same pages here, sir, do you
9 see where I asked:

10 "QUESTION: Sir, is it generally accepted in
11 the scientific community that the effects of niacin on
12 blood lipids reduce the incidence of coronary artery
13 disease?

14 "ANSWER: I can't say what's generally
15 accepted."

16 Do you see that?

17 A. Yes.

18 Q. Did you testify to that effect?

19 A. Yes.

20 Q. On the same page, when I asked:

21 "QUESTION: Why can't you say what's generally
22 accepted in the scientific community in this area?

23 "ANSWER: I'm trying to answer your questions
24 honestly and effectively and accurately, and regardless
25 of whether you like my answer, my answer is an honest

1 answer, and if you want me to say something other than
2 that, I'm not comfortable doing it. I don't know -- I
3 only know what I think. I can't speak for what the
4 rest of the universe thinks, and I don't know what
5 they're reading. I don't know what they're thinking
6 today, and you're asking me this question today."

7 Did you testify to that effect, sir?

8 A. Yes, I did.

9 Q. Sir, you've never been asked to file a new drug
10 application on a sustained release product in Europe,
11 have you?

12 A. No.

13 Q. Sir, you've never personally taken an NDA filed
14 in the United States and transformed it into something
15 that was filed in Europe, have you?

16 A. Personally?

17 Q. Yes.

18 A. No.

19 Q. Sir, you don't know what specific types of PK
20 studies or data would have been required in connection
21 with the filing of an NDA in Europe for a sustained
22 release formulation, do you?

23 A. Would you ask that question again?

24 Q. Yes.

25 You don't know what specific types of PK

1 studies or data would have been required in connection
2 with the filing of a new drug application in Europe for
3 a sustained release formulation, correct?

4 A. Well, that's not really correct, because you
5 put in there -- that's why I asked you to read it
6 again -- what types. If you're asking me -- you know,
7 there's two words in there that are sort of confusing.
8 One is "specific" and the other is "types." I'm not --
9 I'm comfortable with the "types." I'm not comfortable
10 with the "specifics."

11 Q. Sir, in your deposition, you testified as
12 follows, didn't you:

13 "QUESTION: Sir, what type of pharmacokinetic
14 study or data would have been required in connection
15 with the filing of an NDA in Europe for Niacor-SR?

16 "ANSWER: Off the top of my head, I don't know
17 what specific types of pharmacokinetic studies would
18 have been required in 1997 for the -- you know, for a
19 sustained release formulation in the EU."

20 Did you testify to that effect or not?

21 A. Yes, I did.

22 Q. Now, sir, you testified on direct that
23 Upsher-Smith had yet to do any PK studies as of June of
24 '97, correct?

25 A. Had yet to complete any. They did some, but

1 they were unacceptable.

2 Q. Sir, in reaching the conclusion that they had
3 yet to complete any, you overlooked Upsher-Smith's
4 901455 protocol, didn't you?

5 A. I don't even know what that stands for, sir.

6 Q. Dr. Levy, Upsher-Smith's 901455 protocol was a
7 single-dose PK study, right?

8 A. I don't recall -- I don't know the number of
9 that study. I have not seen it referred to as a
10 number. I've seen it -- the documents I've seen have
11 been documents dealing with meetings with and
12 correspondence with the FDA that has blasted the study
13 that was done, the so-called single-dose
14 pharmacokinetic study. I have not ever seen it
15 referred to with a number.

16 So, I don't know if that's the study you're
17 talking about. All I know is that the FDA has not
18 accepted and found inadequate the one PK study they
19 tried to do.

20 Q. Sir, you also overlooked --

21 A. I didn't overlook.

22 Q. -- the 920944-B protocol, didn't you?

23 A. Sir, if you're -- if you're trying to be
24 annoying, you're succeeding, because I've said I don't
25 know the numbers of those studies. In any of the

1 documents I've looked at, I have not seen
2 Upsher-Smith's so-called PK studies referred to by a
3 number. So, if you refer to them as a number, the only
4 thing I can say is no, I don't know those studies.

5 Q. Okay. Sir, on direct, you stated with regard
6 to PK studies that Upsher-Smith "had yet to do any."
7 That testimony was inaccurate, correct?

8 A. No. "Do" means complete an acceptable PK
9 study, and to my knowledge, they never completed a
10 successful -- an acceptable PK study. That is my
11 knowledge of this matter. Doing a lousy study doesn't
12 to me deserve the word "do." It might deserve the word
13 "try."

14 Q. Well, sir, doing a PK study in Schering-Plough
15 is like falling off a log, correct?

16 A. I testified to that, yes.

17 Q. Sir, on direct today, you also testified about
18 stability studies, correct?

19 A. Yes.

20 Q. Sir, are you aware of the ICH stability
21 guidelines for new drug applications?

22 A. No.

23 Q. You don't even know what ICH stands for, do
24 you?

25 A. No.

1 Q. Sir, are you aware that both the United States
2 and the European regulatory authorities adopted the ICH
3 stability guidelines?

4 A. I am not aware of that.

5 Q. Are you aware that both the United States and
6 the EU authorities require the same stability data to
7 support a regulatory filing for a new drug application?

8 A. That I would say is to my current knowledge not
9 correct from -- on the basis of another company with a
10 very similar situation with which I'm currently
11 involved and that has had to do in the EU different
12 types of stability studies.

13 Q. Sir, in connection with the work you're doing
14 for this other client, have you consulted the ICH
15 guidelines?

16 A. That's not been what I've been asked to do. I
17 just know that we've had discussions at a board
18 meeting, and we had to do some additional stability
19 studies for the EU market in relation to this
20 particular product.

21 Q. Sir, in connection with this work you've done
22 for other clients, have you considered the Federal
23 Register Notice of September 22nd, 1994, Volume 59,
24 Number 183?

25 A. No. I don't know what it is.

1 Q. Sir, on direct, you also stated with regard to
2 Pierre Fabre that of the 50-some odd companies that
3 were on Mr. Pettit's list, there was "only one left
4 that had not yet rejected Niacor-SR."

5 Do you remember saying that?

6 A. Yes, I do.

7 Q. You were talking as of June 1997, correct?

8 A. Yes. Actually, if I -- if I may correct my own
9 statement in that, I believe that there were two that
10 had not yet -- I misspoke on that. There was another
11 company, and I'm -- I believe it was Esteve that had
12 not yet turned it down formally.

13 Q. Okay, so you're changing it now, there were two
14 that had not yet formally -- is that what you said,
15 formally turned it down?

16 A. Had not sent a letter saying we're no longer
17 interested or not -- you know, blowing off Mr. Pettit
18 in some other way.

19 Q. So, sir, as of June 17th, 1997, Pierre Fabre
20 had not turned down Niacor-SR, correct?

21 A. To my knowledge, that's correct.

22 Q. They were still in discussions with
23 Upsher-Smith, correct?

24 A. I can't say they were in discussions. They --
25 the only thing that I've seen is a letter that raised

1 two very significant issues in their -- in their
2 meeting, and whether it would have gone any further or
3 to further discussions, I can't say. It was very
4 preliminary whatever it was.

5 Q. Well, this letter you're talking about was
6 actually a memorandum from Vickie O'Neill and Mark
7 Halvorsen to Ian Troup, correct?

8 A. I believe that's correct.

9 Q. And it's reporting on their -- the meeting they
10 had at Pierre Fabre in Paris on June 3rd, 1997,
11 correct?

12 A. I don't recall the date, but that's --

13 Q. And that was a confidential meeting, correct?

14 A. I don't know that.

15 Q. But sir, you do concede that as of June 17th,
16 1997, Pierre Fabre had not formally turned down the
17 Niacor-SR opportunity, correct?

18 A. Correct.

19 Q. And you now concede that Dr. Esteve had not yet
20 turned down Niacor-SR as of that time, correct?

21 A. I believe that was the other company that I --
22 that had not yet turned it -- turned it down.

23 Q. Sir, Lacer had not yet turned down Niacor-SR at
24 that time, correct?

25 A. I don't think that's correct.

1 Q. And they never turned down Niacor-SR, did they?

2 A. I don't think that's correct.

3 Q. And Servier had not yet turned down Niacor-SR
4 as of that time, had they?

5 A. As I said, I -- as I say, I don't think that's
6 correct either.

7 Q. And Searle had not yet turned down Niacor-SR as
8 of that time, correct?

9 A. To my knowledge, that is -- you are incorrect,
10 that they had turned it down.

11 Q. And Pfizer had not yet turned down Niacor-SR as
12 of that time, correct?

13 A. I don't even know if Pfizer looked at it. I
14 don't recall that.

15 Q. And Synthelabo had not yet turned down
16 Niacor-SR as of that time, correct?

17 A. I don't think that's correct.

18 Q. And Fournier had not yet turned down Niacor-SR
19 as of that time, correct?

20 A. No, that's not correct.

21 Q. Sir, do you still have the court pleading there
22 in front of you?

23 A. Yes.

24 Q. Now, sir, this is a lawsuit brought against
25 you, correct?

1 A. I'm not sure whether this is the suit against
2 me or if this is the countersuit against him. I
3 can't -- I can't tell.

4 Q. All right, but let me restate the question.

5 This lawsuit was started by one Tom Myers when
6 he sued you, correct?

7 A. That's correct.

8 Q. And he sued you --

9 MR. SILBER: Your Honor, I object to this line
10 of questioning. Mr. Curran was well aware of this
11 lawsuit before trial. He raised this during -- he
12 learned about it at Dr. Levy's deposition. If he
13 wanted to raise issues concerning this lawsuit with Dr.
14 Levy, he could have done so quite easily after Dr. Levy
15 testified in our case in chief. He's now dredging this
16 out very late in the game for whatever purposes, but
17 they certainly do not seem relevant to anything Dr.
18 Levy has testified to today.

19 MR. CURRAN: Your Honor, if they brought this
20 witness back on rebuttal, he's subject to further
21 impeachment on any grounds.

22 JUDGE CHAPPELL: Well, what's your point in
23 utilizing this lawsuit?

24 MR. CURRAN: Well, this pleading, which has
25 recently become available to us, includes admissions by

1 Dr. Levy through his lawyer in which he admits making
2 inflammatory statements about other individuals. He
3 uses colorful language, and he uses harsh terms, and I
4 want to use this document to show that this witness has
5 a penchant for making harsh statements about other
6 people using inflammatory language.

7 MR. SILBER: Mr. Curran says this document just
8 became available to them. They learned about this
9 lawsuit back in November. The date on this document is
10 January 2, 2002. They knew of this or could have known
11 of this at the time of Dr. Levy's testimony in our case
12 in chief, and I see no reason why this is relevant and
13 why it should be brought up at this time.

14 JUDGE CHAPPELL: I am not going to allow
15 extraneous evidence to impugn the character of this
16 witness. So, I don't want to any more questions about
17 this lawsuit. Move along.

18 MR. CURRAN: Very good, Your Honor.

19 That's all I have for this witness, Your Honor.

20 JUDGE CHAPPELL: Thank you.

21 Redirect?

22 MR. SILBER: Briefly, Your Honor, if I could
23 just have a moment to prepare.

24 JUDGE CHAPPELL: Take a moment, and then go
25 ahead.

1 (Pause in the proceedings.)

2 JUDGE CHAPPELL: Just keep in mind, if you ask
3 anything, they're going to get a chance.

4 MR. SILBER: Well, with that -- I just have two
5 questions.

6 REDIRECT EXAMINATION

7 BY MR. SILBER:

8 Q. Dr. Levy, you've been shown information by Ms.
9 Shores on a variety of other deals in the
10 pharmaceutical industry. After seeing that
11 information, does that change your opinion in any way
12 that the \$60 million noncontingent payment by Schering
13 to Upsher was the largest payment in Schering's
14 history?

15 A. No.

16 Q. And again, Ms. Shores showed you these
17 documents on other deals, some of which post-date June
18 of 1997. After seeing those materials, does that
19 change your opinion in any way that as of the time of
20 this deal, the \$60 million noncontingent payment was
21 the largest in the history of the industry?

22 A. No.

23 MR. SILBER: That's all I have, Your Honor.

24 JUDGE CHAPPELL: Recross based on that minimal
25 redirect?

1 MS. SHORES: Don't I get to go through all
2 those deals -- no, I'm just kidding, Your Honor. No
3 questions.

4 JUDGE CHAPPELL: You can, but we won't be here.
5 Mr. Curran?

6 MR. CURRAN: Nothing further, Your Honor.

7 JUDGE CHAPPELL: Thank you, Dr. Levy, you're
8 excused.

9 THE WITNESS: Thank you.

10 JUDGE CHAPPELL: Ms. Bokat?

11 MS. BOKAT: Yes, Your Honor.

12 JUDGE CHAPPELL: Do you anticipate that you'll
13 be calling one more witness?

14 MS. BOKAT: That's correct.

15 JUDGE CHAPPELL: And that's tomorrow?

16 MS. BOKAT: Yes, Professor Bazerman will be
17 here tomorrow, Your Honor.

18 JUDGE CHAPPELL: And what's the length of your
19 anticipated direct exam?

20 MS. BOKAT: Again, I'm looking at the person
21 who's not in charge of the direct, because he's not
22 here. The best guess of those of us who aren't doing
23 the direct is an hour and a half to two hours on
24 direct.

25 MR. CURRAN: Your Honor, if I could be so bold

1 as to suggest an earlier start tomorrow, I think we're
2 all anxious to make sure this witness finishes
3 tomorrow, and we cannot make a representation at this
4 point really as to how long the cross examination from
5 Upsher-Smith may be. So, if I could suggest a start at
6 10:00 or 9:30, please take that as a good faith
7 statement.

8 JUDGE CHAPPELL: We could do that, but it seems
9 that if you have all day, you fill the space. Has
10 anyone noticed that? I think we will go at 10:00
11 tomorrow.

12 MR. CURRAN: Thank you, Your Honor.

13 MS. BOKAT: Your Honor, could I raise a couple
14 of things before we adjourn for the day?

15 JUDGE CHAPPELL: Go ahead.

16 MS. BOKAT: I have a written proffer. This is
17 in lieu of the testimony of the gentleman from
18 Walgreens, Mr. William Groth. We would like to make a
19 proffer. It's in the form of a sworn declaration that
20 we have labeled CX 1778.

21 JUDGE CHAPPELL: That will be admitted for
22 identification only.

23 MS. BOKAT: Right. May I give copies to the
24 court reporter and to opposing counsel, please?

25 JUDGE CHAPPELL: Yes, you may.

1 Regarding offers of proof, I was just going to
2 bring that up, Ms. Bokat.

3 MS. BOKAT: Yes, Your Honor.

4 JUDGE CHAPPELL: On evidence that has been
5 offered by you and excluded by me, I expect to have
6 those filed by the end of the day tomorrow. Does
7 anyone object to that?

8 MS. BOKAT: Okay, so any proffers from
9 complaint counsel should be made before the end of the
10 day tomorrow?

11 JUDGE CHAPPELL: And remember, I clarified it
12 by saying of evidence offered by a party and excluded
13 by me. That would -- that's my definition of what you
14 would offer, and that's what the rule says, but is
15 there anyone who can't have those ready by the close of
16 business tomorrow?

17 MS. BOKAT: May I have one minute, Your Honor?

18 JUDGE CHAPPELL: Yes, I mean I understand that
19 Bazerman hasn't testified yet and I may sustain
20 objections tomorrow, but you know I've excluded his --
21 was it his supplemental report?

22 MS. BOKAT: Yes, his supplemental expert
23 report.

24 May I have just one minute, Your Honor?

25 JUDGE CHAPPELL: Go ahead.

1 (Counsel conferring.)

2 MS. BOKAT: Your Honor, we know that there's a
3 proffer -- a written proffer on Professor Bresnahan
4 that's in the works, and we may need a proffer for some
5 of the material of Dr. Levy that was excluded today.
6 So, I was wondering if we could have until 9:30 Monday
7 morning to submit those. Those will all be written.

8 JUDGE CHAPPELL: Well, here's my thinking: At
9 the end of the day tomorrow, if we have no more
10 witnesses -- and let me just question the respondents.
11 Do you anticipate any further witnesses from your side?

12 MR. NIELDS: We certainly don't at this point,
13 Your Honor, and I'd be very surprised if it changed.

14 MR. CURRAN: Likewise, Your Honor.

15 JUDGE CHAPPELL: What I intended to do was at
16 the end of the trial tomorrow designate a day by which
17 I will close the record, and then if requested by the
18 parties, we would get together again one more time.

19 I have gotten the joint motion filed by the
20 parties. I appreciate it. I haven't decided yet -- I
21 anticipate I'm going to rule on that. I am going to
22 grant it, so don't panic. I am going to allow the
23 argument after the briefing.

24 MS. BOKAT: Thank you for mentioning that.

25 JUDGE CHAPPELL: But I think you have been a

1 little too liberal in the time you're allowing
2 yourselves for briefing. I'm probably going to
3 compress that a little more, not a whole lot more, but
4 I want to leave myself time to review the briefs so
5 that I may ask what at least I think are some
6 constructive questions during the argument.

7 So, I'm going to grant the motion. I'm not
8 doing it now on the record, but I intend to roll that
9 into my order closing the record for evidence. And
10 while we're on that topic, I want to advise all the
11 parties, the record will be closed, so any
12 demonstrative exhibits, charts, paraphernalia you want
13 to refer to in your closing will not be part of the
14 record, just keep that in mind, for identification or
15 otherwise.

16 And getting back to your question -- I don't
17 want to be nonresponsive, Ms. Bokar -- if the proffers
18 are allowed to be made or if there are any that aren't
19 ready by tomorrow, they can be made by the day I close
20 the record, which I anticipate to be Tuesday or
21 Wednesday. I think the parties requested Tuesday. I
22 don't expect -- what I'm not looking for is someone who
23 forgot an offer to try to bring in new evidence. I'm
24 looking for a typo or correction, something that you
25 find in the transcript, something that was mismarked or

1 mishandled, ministerial things.

2 I'm just wondering if it would be a shame for
3 all of us to need to get together again, although I
4 really enjoy everyone's company, one day next week,
5 just for the purpose of offers of proof. That's a
6 question.

7 MS. BOKAT: I'm wondering whether -- if the
8 written proffers, if we could just submit them, file
9 them somehow without having to get everybody together
10 in the courtroom.

11 JUDGE CHAPPELL: Well, after tomorrow, they're
12 going to be written.

13 MS. BOKAT: Right.

14 JUDGE CHAPPELL: Or there won't be any.

15 MS. BOKAT: That's a very good point.

16 MR. CURRAN: Your Honor, just for Upsher, we
17 don't think it's necessary to get together for purposes
18 of the offers of proof. We'd be happy to come.

19 JUDGE CHAPPELL: The only reason I'm bringing
20 that up is I think it was Mr. Gidley who was somewhat
21 adamant about cross examining an offer of proof. I'm
22 not sure the rules even allow that, but if you turn in
23 the offers the day I close the record, there will be
24 none of that.

25 MR. CURRAN: We understand that, Your Honor.

1 Mr. Gidley, who I think may have been acting on my
2 prompting at that time, we were reacting to the sudden
3 notion of this offer of proof. We hadn't thought it
4 all through. We have now, and we understand that cross
5 examination is not necessary with regard to those.

6 JUDGE CHAPPELL: So, then, what I'm hearing is
7 everyone agrees jointly that any written offers of
8 proof could be filed prior to or the day that I close
9 the record? Is that what I'm hearing?

10 MR. CURRAN: That's fine with Upsher-Smith,
11 Your Honor.

12 MR. NIELDS: Yeah, that's fine with us, Your
13 Honor.

14 MS. BOKAT: That's fine with complaint counsel,
15 Your Honor.

16 JUDGE CHAPPELL: But then how do you envision
17 filing them, with Donald Clark, the Secretary's Office,
18 or with Susanne, the court reporter, which was my
19 question earlier, whether we all need to get together
20 just for that act.

21 MS. BOKAT: Yeah, the logistics question. I
22 guess we would need to get a copy to the court
23 reporting company.

24 JUDGE CHAPPELL: Well, let's put it this way.
25 Somebody has to make a decision here. I guess it's me.

1 If the offers aren't ready by tomorrow and there are
2 any further offers, we're going to get together,
3 probably for a short time, and we won't need all this
4 high-paid, high-powered legal talent that I see in
5 front of me now. One representative from each party
6 will suffice. Any questions?

7 MS. BOKAT: If we are not highly paid, can we
8 have more than one?

9 JUDGE CHAPPELL: It's -- that would include
10 more than one judge, right? But whatever you prefer.
11 Anything further today?

12 MS. BOKAT: Yes. On a housekeeping matter,
13 we've received a request to remove our binders of
14 documents from the courtroom after the last witness,
15 which we will certainly do. We had one question. We
16 had prepared a set of exhibits for the Court, and we
17 don't know whether you still want a set, but we -- if
18 you do, what we would probably do would be to
19 double-check it to make sure it's complete and then
20 have it early next week, if --

21 JUDGE CHAPPELL: I don't need a set if things
22 are properly referred to in post-trial briefs and
23 they're in evidence. I think what I would prefer is if
24 you're going to do something like that, then all I'm
25 going to need are the exhibits to your post-trial

1 briefs. I'm assuming that all the exhibits in this
2 case won't be that important to the post-trial briefs.
3 So, that would -- that would preclude some copying at
4 least.

5 Regarding post-trial briefs, I would strongly
6 suggest for all sides when you file a reply that you
7 address the points raised in the opposition's brief in
8 the same order that they have been raised. It makes it
9 a lot easier to follow the arguments. It makes it a
10 lot more persuasive for all concerned. Any questions
11 on that?

12 MS. SHORES: I do have one, Your Honor.

13 JUDGE CHAPPELL: Okay.

14 MS. SHORES: Although maybe it's a stupid
15 question, it probably is. In fact, I know it is given
16 the briefing schedules. Dumb question, withdrawn.

17 JUDGE CHAPPELL: It's better to refer to a
18 stupid question and withdraw it then go ahead and ask
19 it, I believe. You are going to go ahead and ask it
20 anyway, aren't you?

21 MS. SHORES: I usually think of stupid
22 questions after you've left the courtroom.

23 JUDGE CHAPPELL: Does everyone understand what
24 I'm looking for in the way of reply briefs?

25 The other thing regarding reply briefs -- I was

1 going to do this tomorrow, but I'll go ahead and cover
2 some of these things today. When in camera material is
3 used in the post-trial briefs, you must put brackets
4 around it or highlight the in camera information, and I
5 know with word processors you can shade it or do
6 something, but that hasn't been done thus far in some
7 of the briefing I've seen. I don't think you want to
8 make me go through the whole record to find out whether
9 something was in camera or not, so I'm asking for your
10 assistance.

11 I want to be able to rely on the post-trial
12 briefs I get from the parties if you use something
13 that's in camera so that I can get the opinion out and
14 the decision out a lot quicker that way.

15 Also, when you file the reply briefs, I noticed
16 in your motion you had asked for 11 days. I'm leaning
17 toward giving you more time than that. Would anybody
18 object to that?

19 MR. NIELDS: I'm doing some math, Your Honor.
20 Does that mean -- if we have more time for the reply
21 brief, does that mean we have less time for the opening
22 brief?

23 JUDGE CHAPPELL: Yes. Not a lot more, a half a
24 week maybe.

25 MR. NIELDS: Half a week less?

1 JUDGE CHAPPELL: Right. That's why I'm asking
2 you if you have a preference. I understand how you've
3 requested it in your filing. If you had the time,
4 you'd prefer to have it on your opening brief rather
5 than your reply brief?

6 MR. CURRAN: I think we would, Your Honor,
7 Upsher-Smith.

8 You can disagree.

9 MR. NIELDS: We seem to be short of unanimous,
10 Your Honor, but I think the majority view is yes,
11 perhaps the opening brief -- perhaps the opening brief
12 is more -- going to be more time -- is going to require
13 time more than the reply. We should have pretty much
14 surrounded the information is my guess, and the reply
15 brief is going to be analysis and response but not as
16 much -- require from our point of view as much time.

17 MS. BOKAT: I would concur.

18 JUDGE CHAPPELL: Well, I'm glad I asked.

19 All right, that's all I have. Anything
20 further?

21 MS. BOKAT: One other thing just in the timing.

22 JUDGE CHAPPELL: Didn't you say one other thing
23 two things ago?

24 MS. BOKAT: No, Your Honor.

25 JUDGE CHAPPELL: I'm kidding, go ahead.

1 MS. BOKAT: One thing I learned early was don't
2 count.

3 Just for the purposes of thinking about
4 tomorrow's timing, there are a few remaining exhibits
5 that complaint counsel plan to offer as part of our
6 rebuttal case. We've been trying to work out a
7 stipulation with the parties, but it may be that there
8 will be a few on which there isn't a stipulation, so we
9 may need a few minutes to address the offer of those
10 exhibits.

11 JUDGE CHAPPELL: I think I may, to the extent
12 there are any of those exhibits, I think I may hear
13 that first thing so that I can contemplate during any
14 breaks tomorrow and rule accordingly. So, be prepared
15 to offer that -- those exhibits first thing tomorrow at
16 10:00.

17 MS. BOKAT: That's helpful to know. That way
18 we can have the appropriate personnel here on time.

19 JUDGE CHAPPELL: Okay.

20 MR. NIELDS: Your Honor, I guess I have a
21 logistical issue that I'm not positive I know the
22 answer to yet, but some of the exhibits that Ms. Bokat
23 is referring to I believe are deposition transcripts.
24 Some of them, I believe I'm right about this, we only
25 learned about either late last night or early this

1 morning.

2 I'm not positive that we're going to be in a
3 position to have counter-designated by tomorrow
4 morning. We will make every effort to do that, but I'm
5 just not certain that we will be in shape. I had
6 actually originally thought that we would be getting
7 together at least one day next week and that perhaps if
8 we couldn't work it out by agreement, we would have
9 until then.

10 JUDGE CHAPPELL: Well, and to make my ruling
11 more -- I guess less complex, then it sounds like
12 you're going to want to file an expedited motion to
13 exclude?

14 MR. NIELDS: With regard to these --

15 JUDGE CHAPPELL: To the extent you don't agree
16 on all these exhibits, for whatever reason?

17 MR. NIELDS: I guess, Your Honor, I'm simply
18 not yet in a position to know whether we're going to
19 have a disagreement --

20 JUDGE CHAPPELL: And I'm just trying to figure
21 out whether you're planning to just object to these
22 exhibits or move to exclude them for some other reason.

23 MR. NIELDS: I certainly was hoping not to file
24 a brief or anything of that nature, Your Honor.

25 JUDGE CHAPPELL: I think Ms. Shores is dying to

1 tell you something.

2 MR. NIELDS: Yes, she probably is.

3 MS. SHORES: I'll just go out on a limb here
4 and speak for Schering. If what Your Honor was
5 contemplating was something in writing would give us
6 more time and then we wouldn't have to get together, we
7 could conceivably address it that way.

8 JUDGE CHAPPELL: Well, it -- my concern I guess
9 is if you're telling me there's surprise here and you
10 didn't know about this, then I'm trying to figure out
11 what the fair thing is to do for all the parties, and I
12 could move the last day of -- I could close the record
13 maybe Thursday.

14 MR. NIELDS: Oh, I don't have a problem with
15 Tuesday. We can -- what we need -- what we will need
16 is time to have our discussions with complaint counsel
17 to see if we can agree on things, and if we -- if we
18 can't, we'll know that in time to deal with them, Your
19 Honor, Monday or Tuesday or Wednesday of next week at
20 the Court's pleasure.

21 The other thing that we would -- may need time
22 on is if there are counter-designations that are needed
23 for the deposition designations that complaint counsel
24 has made. That requires us to read through the
25 transcripts and make sure we've counter-designated

1 everything that's needed, and I was just worried about
2 being able to do that reliably by first thing tomorrow
3 morning.

4 I guess what I'm -- I guess my --

5 JUDGE CHAPPELL: Well, do you think you'll be
6 able to do it by the end of the day tomorrow?

7 MR. NIELDS: There is a greater chance of that,
8 Your Honor --

9 JUDGE CHAPPELL: Because I would rather have
10 the parties work out what you can work out before
11 someone stands up and offers a boatload of things and
12 the other side hasn't had a chance to try to work it
13 out.

14 MR. NIELDS: Exactly.

15 JUDGE CHAPPELL: It's a lot more efficient to
16 try to work it out together first, let me know what you
17 can't work out.

18 MR. NIELDS: My guess is it would be more
19 efficient if we were able to have the weekend to try to
20 work things out with complaint counsel, make our
21 counter-designations, make sure they don't have
22 objection to those, and either have nothing in dispute
23 or if there is something it will be very narrow, but I
24 know the Court was hoping not to have to get together
25 at all next week, and it's possible we could --

1 JUDGE CHAPPELL: Well, no, if we have a reason
2 to get together, we'll get together, and if I need to
3 rule on one last evidentiary motion, I will do that. I
4 just don't like to have to rule on the run, seat of the
5 pants. I like to have time to contemplate these
6 rulings.

7 MR. NIELDS: Perhaps -- perhaps what we could
8 do, Your Honor, is see how much we can resolve by
9 agreement by the end of the weekend. If there is
10 anything on which we do not agree, we could file a
11 brief, one-page document advising the Court of what
12 those issues are, and then we could get together a day
13 or two after that.

14 JUDGE CHAPPELL: Ms. Bokat?

15 MS. BOKAT: I see the wisdom of taking a little
16 more time to try and resolve things, and another
17 possibility might be to tentatively set a date when we
18 could get together, Tuesday or whenever, and then if we
19 can work things out among us, we could always notify
20 the Court that there is no need to convene. That's
21 just another possibility.

22 JUDGE CHAPPELL: Right, and I'm operating under
23 the rule that requires me to close the record
24 immediately, but I've got to construe "immediately" to
25 mean immediately upon -- the parties haven't had time

1 to look at obvious errors in the transcript or exhibits
2 misnumbered or a last final evidentiary offer. To me
3 that comes within the definition of "immediately." So,
4 we could get together perhaps Tuesday and then perhaps
5 again on Wednesday to just finalize everything.

6 I mean, there is no magic bullet. There is no
7 magic number that we have to end everything on Tuesday.
8 So, I think I'll let everybody talk about the exhibits
9 I know nothing about right now and report to me
10 tomorrow, at some point tomorrow, either the beginning
11 of the day or later in the day.

12 Any objections to that?

13 MS. BOKAT: No, Your Honor.

14 MR. NIELDS: No, Your Honor.

15 MR. CURRAN: No, Your Honor.

16 JUDGE CHAPPELL: Okay, Mr. Curran?

17 MR. CURRAN: I was just saying no objection to
18 that.

19 JUDGE CHAPPELL: Thank you. Then we're
20 adjourned until 10:00 a.m. tomorrow.

21 (Whereupon, at 4:50 p.m., the hearing was
22 adjourned.)

23

24

25

1 C E R T I F I C A T I O N O F R E P O R T E R

2 DOCKET/FILE NUMBER: 9297

3 CASE TITLE: SCHERING-PLOUGH/UPSHER-SMITH

4 DATE: MARCH 21, 2002

5

6 I HEREBY CERTIFY that the transcript contained
7 herein is a full and accurate transcript of the notes
8 taken by me at the hearing on the above cause before
9 the FEDERAL TRADE COMMISSION to the best of my
10 knowledge and belief.

11

12 DATED: 3/22/02

13

14

15

16 SUSANNE BERGLING, RMR

17

18 C E R T I F I C A T I O N O F P R O O F R E A D E R

19

20 I HEREBY CERTIFY that I proofread the
21 transcript for accuracy in spelling, hyphenation,
22 punctuation and format.

23

24

25 DIANE QUADE

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